Summary Report

Putting Research to Work in Quality Improvement and Quality Assurance

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Foreword

The Agency for Health Care Policy and Research (AHCPR) is the Federal Government's focal point for health services research, including medical effectiveness research. AHCPR's mission is to enhance the quality, appropriateness, and effectiveness of health care services and improve access to such services, through a broad base of scientific research and the promotion of improvements in clinical practice and in the organization, financing, and delivery of health care services.

AHCPR has a strong commitment to research on quality of care measurement and development of quality assurance methods. AHCPR will support research on these and related issues as part of its continuing effort to integrate knowledge on the effectiveness of health care into clinical practice.

To help refine a research agenda responsive to current needs, AHCPR convened a conference in March 1992 to examine research priorities in quality improvement and quality assurance. The conference provided a forum for discussion among health care providers, researchers, policymakers, and quality improvement and quality assurance professionals working in both public and private delivery settings. This volume contains commissioned background papers, presentations, summaries, and recommendations from the conference.

We hope this report will stimulate research and further discussions that will improve the science base for developing quality improvement and quality assurance initiatives.

J. Jarrett Clinton, M.D., M.P.H.
Administrator
Agency for Health Care Policy and Research

Preface

The publication of this report marks what we hope is the beginning of a broad-based and innovative quality assurance and quality improvement research program that will build on the work already underway at the Agency for Health Care Policy and Research (AHCPR). As efforts to further health care reform take shape, it is clear that measuring, assuring, and improving quality of care will be critically important and require a concerted research effort.

This report includes background papers and commentary summarizing the issues raised at the 1992 AHCPR working conference designed to formulate a research agenda on quality assurance and quality improvement. The commissioned papers provide a comprehensive overview of the conceptual and practical issues involved in building a science base to support quality improvement. They include extensive references to current literature and descriptions of innovative programs. The papers and commentary also pinpoint some concerns about definitions and information gaps and highlight issues regarding the roles of medical professionals, payers, and health care consumers in quality assurance and quality improvement.

We believe that the wide range of experiences and interests articulated during the conference are vital to the creation of a meaningful research agenda. Developing measures and data to generate better information on quality of care was stressed throughout the conference. There was also general agreement among conference participants on the importance of investigating the effects of quality improvement and identifying which mechanisms, processes, or models "work" in different circumstances.

There was less consensus on a taxonomy for quality-related activities and the optimal relationships and contributions of quality improvement and quality assurance. Similarly, opinions regarding the use of information by health professionals, peer reviewers, regulators, payers, purchasers, and consumers often reflect the distinct perspectives of the authors and conference participants. Nevertheless, important research issues were identified in all areas.

AHCPR is actively pursuing a research agenda designed to identify the most effective ways to prevent, diagnose, and manage health care problems and to communicate that knowledge to practitioners and patients. The development of clinical practice guidelines, medical review criteria, performance measures, and standards of quality mandated by AHCPR's authorizing legislation are important tools for quality assurance and quality improvement. Related research on methods and measures and the effects of quality improvement is important.

The conference also brought to light the need to expand the horizons of health services research beyond the areas noted above. Participants emphasized the need to understand more about how health care organizations, coalitions of providers and purchasers, and delivery systems work, so that the new technologies and methods of quality improvement are introduced successfully. Priority issues generated in the workshops include the further development and evaluation of information technologies and the need to describe and evaluate what is happening within organizations with respect to health care quality improvement, peer review, utilization management, and other mechanisms to enhance quality of care. Organizational structure, climate, and leadership are potentially important variables, as is the external regulatory and reimbursement environment. Basic data collection, descriptive research, and experimental studies are needed to strengthen the science base for quality assurance and quality improvement. We believe this summary report will contribute towards that end.

Linda K. Demlo, Ph.D.
Director, Office of Program Development
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Executive Summary

Introduction

This volume summarizes research issues in quality improvement and quality assurance, which were examined in detail during an agenda-setting conference on "Putting Research to Work in Quality Improvement and Quality Assurance," sponsored by the Agency for Health Care Policy and Research (AHCPR) in March 1992. The conference provided a forum for interaction among health care providers, researchers, policymakers, and quality improvement and quality assurance professionals working in both public and private delivery settings. Participants examined the state of the art and discussed how better to structure research and development to strengthen the effectiveness of quality improvement (QI) and quality assurance (QA) activities and their responsiveness to underlying needs of health care delivery and public policy.

While there are a variety of definitions of quality review, a working definition emerged over the course of the conference. The concept of QI was used to refer to a set of specific approaches to improving performance, as indicated by objective measures, using techniques such as organizational redesign, cross-functional management, processes of continuous improvement such as QI teams, and a focus on defining customer-oriented system objectives. QA was used to refer to internal and external methods for assessing the incidence or levels of quality problems and assure that quality is achieved.

The conference focused on four major themes:

- **Methods and measures,** including quality review criteria, performance standards, and ways to improve the science base in these areas.
- **Information technologies,** including automated data resources and medical informatics.
- **Organizational issues,** including relationships with health care delivery systems, control and responsibility for quality review, and resources for QI and QA.
- **Using quality-related information,** including the roles of patients and purchasers as their agents (for example, consortia of employers that negotiate with providers) in acquiring and using quality-related information and the influence of the information on both clinical decisionmaking and the behavior of health care institutions.

Conference speakers, panelists, and workshop participants identified common themes:

- Information technologies are both a driving force behind and a major source of concern in evolving QI/QA systems.
- The field of quality improvement—total quality management and continuous quality improvement—holds promise for major changes in organization and practice, but there is currently little sound evidence of its effects on either health care outcomes or delivery system efficiency.
- There is a strong interest across the practice, research, and payer communities in retrospective and prospective evaluations of models for improving quality of care. Evaluations are needed to identify what aspects of QI/QA methods and models work or do not work in different organizational environments and the factors that facilitate or hinder their effectiveness.

The priorities for research developed in the workshops and discussed in this volume generally reflect these basic themes.

Methods and Measures

Improved methods and measures are essential if expanding knowledge about medical effectiveness is to be translated into better medical management. Conference participants addressed research issues in the following areas: quality review criteria, performance standards, and the science of quality assessment and improvement. Key questions requiring attention are:

- **Medical review criteria.** What are the best methods for developing, implementing, and evaluating medical review criteria? How do national and local criteria compare? How do criteria developed from the generalist perspective compare with those developed from the specialist perspective in terms of acceptability and usefulness? What are the best ways to design and apply clinical guidelines and review criteria across sites of care, taking into account the locus of responsibility for decisions and differences in

the configurations of practitioner settings? What sampling strategies are most effective for specific applications?

- **Changes in practice behavior.** What are optimal methods of information feedback for both practitioners and systems to change practice? Which elements of practice are most amenable to change?
- **Clinical guidelines.** How does implementation of clinical guidelines affect quality of care? What difference do guidelines make in terms of cost and patient outcomes, including functional status?
- **Measuring quality of care.** In addition to data from the medical record, what other data on the process and outcomes of care should be captured, compared, and contrasted to improve the quality of care? What longitudinal measures of quality of care best characterize patient care episodes across the complete range of practice settings? What are the strengths and weaknesses of profiling methods as QA tools? What is known about the validity of commonly used measures of quality of care? Are there methods to improve the reliability and validity of measures of quality?

Information Technologies

Research priorities for information technologies focus on availability, quality and specificity of data for quality assessment and on specific ways to address the social, political, and other barriers to using information technologies. Research questions include:

- **Automated information systems.** How effective are automated information systems as tools for improving the quality of patient care? How are the data in information systems used, and what other data elements should be included to improve the systems, quality measurement, and quality of care? How may patient-specific probabilities and utilities be incorporated into decision support systems?
- **Use of information system technology.** What are the factors that influence the adoption of information systems technology in QI and QA programs? What is known about the roles of technology, policy, legislation, and public opinion in solving the problems of privacy and confidentiality of electronic records?
- **Diffusion and dissemination.** What are the most effective ways of diffusing QI/QA technologies that improve quality and dissemination of the information derived from these systems?

Organization of QI/QA Systems

Research on the organization of QI and QA systems is critical to incorporate methods and measures effectively into ongoing programs. Relevant issues include organizational readiness and capacity to accept and use new methods and technologies, institutional and professional culture, and public demands and expectations. Research also is needed on how different approaches to designing and implementing QI can be structured to work in different health care delivery settings, how responsibility for monitoring quality is allocated among internal and external review entities, and what resources are needed to assure and improve health care quality. There is a particular need for descriptive and comparative information on what is happening in quality review systems throughout the country, as well as a need for more information on State and Federal regulation, accreditation programs, and certification systems. A variety of questions require research and evaluation, including:

- **Organizational structure.** Are certain organizational structures able to more readily adopt QI methods and programs? What models (or delivery systems) employ the tenets of QI most easily and why?
- **Effects of QI.** What have been the measurable effects of QI on the cost, quality, and effectiveness of the health care provided by organizations using QI? How have improvements been achieved?
- **Oversight and review of QI programs.** What are the effects of oversight? How may an optimal relationship between an external and internal review of quality of care in a delivery setting be identified? How does external review stimulate, support, or subvert the QI process?
- **Management variables.** Which management variables (including both professional and administrative services) that affect how the process of care is organized and how decision-making occurs also affect the outcomes of care?

Using QI/QA Information

QI/QA information has been suggested to be a key to managed competition approaches to health care and innovations such as health insurance purchasing cooperatives. Particularly important research questions are:

- **Communication.** What information about patient experiences can clinicians and provider organizations use to improve care? What are the characteristics of patient-provider communication that lead to improved outcomes? How can the medical encounter be structured to enhance effective patient-provider communication?
- **Use of data.** How do patients and purchasers of health care use data on the quality and effectiveness of health care? What are the effects of that information on patient health-related behavior, health-care-seeking behavior, anxiety levels, and satisfaction with care?
- **Informed decisionmaking.** What information do patients and purchasers need to make informed decisions about the quality of care they can expect when selecting health care providers? How can they be well-informed about the interpretations and uses of QI/QA data?
- **Purchaser-provider partnership.** Are there examples of purchaser-provider partnerships for achieving QI/QA goals? If so, what are their unique characteristics? For example, is success in achieving the goal of demonstrated savings for the purchaser associated with such characteristics as providing information about quality to consumers?
- **QI/QA and the community.** Can QI make a contribution to fostering integrated models of community health service delivery? Does QI provide common measures and tools for linking all participants? Can QI make a contribution to the community? How can barriers to comparison of QI/QA information across organizations be addressed?

Conclusion

AHCPR plans to support research on these and related issues as part of its continuing effort to integrate knowledge on the effectiveness of medical care into medical practice. The recommendations found in this volume will be incorporated into AHCPR programs and used to establish priorities for new research, demonstrations, and/or evaluation initiatives.

National Health Policy, Quality Research, and Total Quality Improvement

Helen L. Smits, M.D.

National Health Policy

I will begin with my version of the list of problems in our health system: access, cost, the hassle factor, and manpower. The first two items, access and cost, are universal. If you ask knowledgeable individuals what is wrong with our health care system, the consensus seems to be that cost and access are our two most serious problems.

Hassle factors and manpower appear on the list as somewhat eccentric additions of my own. By hassle factors, I mean all the elements that can make it extremely unpleasant to be either a patient in the U.S. system or to practice medicine in it, especially in that supposedly valued area of practice, primary care. If you doubt that we are unusual in this area I would urge you to spend time, as I have, talking both to practitioners and residents of other countries who have been patients.

I have an elderly father whose medical conditions are beginning to catch up with him. I visit him in New York every month or so. The first event of every visit is the presentation to me of a file of Explanation of Benefit forms, mostly with denials of claims. My stepmother is British by birth, and she finds this aspect of American culture baffling. We are doing pretty well; the folder is getting thinner. But requiring an 84-year-old man to write four letters to prove that he has Medicare Part B when he has faithfully paid those premiums for 19 years is nonsense and a terrible waste of money. I am pleased to report that I have now given them the greatest possible assistance they could have asked for: I have found him a primary care physician who accepts assignment.

Hassle factors include the terrifying implications of access for many working Americans. I doubt that many at this conference are either self-employed or employed by small companies. I have the great privilege of living in a small town in Connecticut where there are many self-employed individuals and many who work for small businesses. These people share a common sense of gloom about the potential loss of health insurance or the potential escalation of premiums into an unaffordable range.

Finally, manpower. This is not a fashionable worry these days, given the depths of our recession and the fact that many women have returned to nursing or have increased their work time, thus reducing the shortage we faced only a few years ago. But the reality is that the out-year projections are frightening. This is particularly true in areas other than nursing such as laboratory technology and x-ray technology. We suffer as health care employers from the pervasive problems that plague the American educational system. In my own city of Hartford it is not clear who will be available in 10 or 15 years for the technologist jobs, given the weakness of our high schools.

Total Quality Improvement

There are many who know more about total quality improvement (TQI) than I do. What I have to offer is a personal perspective that comes of having wrestled with the issues as a member of the board of the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), as the director of a hospital that is beginning to lay out a plan for TQI, and as a participant in a number of training sessions and seminars.

To me, the most exciting thing about TQI is not its radical qualities but the opportunity it gives us to rework activities we are already engaged in and understand. First, TQI requires many of us to acquire skills that we used to leave to the management engineers. You must fully understand the process, and you are given straightforward tools to facilitate your understanding. TQI couples those tools with the concept that front-line employees should solve the problems presented by their work. If your objective is to correct a problem in same-day surgery, such as delays, you ask the clerks, doctors,

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and nurses to work together to figure out what is wrong, and you offer them the opportunity to fix it themselves.

Another attractive element of TQI is the concept that hospitals should satisfy their customers, both internal and external, and that satisfaction should be rigorously measured. If you work in the billing office, part of your job is to be sure that people understand the bills they receive and are satisfied, as much as anyone can be, that the billings are fair and honest. In addition, you must satisfy internal customers who need information about volume and revenues. If all the elements of an organization are one another's customers, and if the services that we provide to one another must be of the highest quality, then the way we treat one another will change radically.

Finally, at the heart of TQI is the concept that quality can be both measured and reported. Aggregated reports, just like financial reports, can be provided to the hospital board, and more detailed information can be provided to the chief executive officer and individual department heads. These reports on quality constantly remind us: Where is it this month? Where was it last month? Where do we want it to go?

While this sounds ideal, it has not yet been proven in health care. There are some hospitals that are several years into the process and enthusiastic about the results, but I have yet to hear of any hospital that can report results as dramatic as the Plexiglas® manufacturing plant in Connecticut that has been deeply involved in TQI for 10 years. They have documented improvement in efficiency of several hundred percent and a documented drop in employee turnover and employee dissatisfaction. You have to believe that TQI will continue with a track record like that. We have not reached that point in health care, although we are working hard to get there.

Barriers to TQI: A Research Agenda

I recommend that the design of a TQI research agenda begin with an examination of the barriers to TQI in health care. First, there is the problem of rigidly defined professional roles. TQI will not work if the team decides that the nurse could obtain some insurance history while she is collecting medical information and the nursing office vetoes the idea on the grounds that insurance is "not a nursing job." Or, conversely, it will not work if the team wants to train clerks to take blood pressures, but the idea is vetoed because that is a nursing job. The ability to exchange roles and the ability of front-line workers to define and control what they do is a very important part of TQI.

The Plexiglas® plant requires that everyone on the assembly line be trained to do all jobs. The company vice president who serves as on-site manager also can do everything. The work groups have decided to organize their lives to suit themselves. The plant is organized into two permanent 12-hour shifts, and work teams are unique to one shift or the other. The day-shift group has decided that it likes to change jobs frequently, so every 4 to 6 weeks day workers move on to a different task. Night-shift employees seem more set in their ways; they shift tasks only every quarter or every 6 months. It may sound like a small difference, but it provides an enormous sense of control to the workers on both shifts. I am still looking for the hospital where nursing staff can handle task assignment so differently from one nursing unit to another.

Formal external regulation is another serious barrier to TQI. The more specific and detailed the regulation, the more difficult it is to enforce and the larger the barrier it presents to improving the institution. One of my favorite examples is the Federal requirement that nursing home medication orders be rewritten every 30 days. I know how to get them written approximately every 30 days: hold a doctor's coffee hour on the second Tuesday of every month, and ask that orders be rewritten at that time. All of us schedule by months and think in months; a "second Tuesday" is easy to block out in a schedule and is likely to work well. The problem is that the regulators will find the home in violation because in some months the time between orders will be 5 weeks instead of 4. Does it matter? Is the time spent enforcing a 30-day rule really worth it? I do not think so.

The problem of rigidity of regulation is far worse in nursing homes than in hospitals, but we certainly find it in hospitals as well. Hospitals suffer particularly from the difficulty of conflicting rules and requirements for different payers. The more time you have to spend remembering to contact this health maintenance organization on day 3, and that one on day 5, the less time you have to work on the internal problems that lengthen hospital stays.

Confidentiality of the oversight data is another interesting issue that to date has received too little discussion. In a Plexiglas® plant there are no problems inherent in letting everyone know what the error rate is or how many units shipped have been rejected by purchasers. But telling the cleaning personnel that the infection rate has risen in the operating room—an outcome they have good reason to know about—is a very different matter.

I am personally sensitive on this issue because I run a State-owned hospital, and no one bothered to exclude us from Connecticut's Freedom of Information Act (FOIA). This means that a plaintiff's lawyer with a case related to infection could use FOIA to try to obtain internal information on our infection rates. As a result, we are very cautious in distributing information and very careful to keep it within conventional quality assurance (QA) channels. I think this issue is relevant for any health care institution. If you send a note to 800 employees saying they improved in one area last month and got worse in others, the chances are that sooner or later those sheets will end up in a lawyer's hands. I believe this problem deserves much more attention and discussion than it has yet received.

Finally, every hospital interested in TQI has a problem in deciding how to work with the medical staff. They are part of the system and, at the same time, not part of it. You cannot require them to attend training courses or take the time to work in groups to solve the problems they complain about. If TQI goes forward without them, there will be problems, but at the same time it is difficult to get them to be as involved as they should be. I believe that TQI offers an opportunity to rework the doctor-hospital relationship in a way that is beneficial to both sides, but it is not going to be easy. Working towards that end is going to take time and money for all of us.

Research and TQI

How does quality research support TQI? First, we need measurement tools. In many instances, an instrument that works well for research purposes—such as a survey form—can, with care, be adapted to monitor day-to-day performance. But the technology transfer to ordinary use does not just happen; questions about the form's length and the training needed to administer it must be considered first. Interestingly, the greatest efforts to produce practical measurement tools have been carried out by for-profit consultants with results that are not made public. I think we need more public effort to develop workable measurement tools for common use and more reporting of results on all of the instruments now in use so that institutions can make sensible decisions about what to use when.

We also need help in defining professional roles and examining the rigidities that separate them. Whether or not we use TQI tools for improvement, we need help in looking at which tasks within a hospital or a home health agency can be shared in and identifying those barriers to smooth function we have created.

Next is the problem of affordable data systems. I am constantly astonished by the amount of money hardware and software vendors expect to make in this country from the movement toward TQI. I spoke last fall at one of the annual conferences of the International Society of Quality Assurance. The attitude of those who work in other countries, even relatively wealthy countries, is very different from ours. They are interested in doing the most they can with the data they have; they want to maximize use of their relatively simple collection systems before they add more data points.

I have always been a great admirer of the basic research behind diagnosis-related groups (DRGs) because of the conceptual elegance involved in designing a classification system that uses only data elements already collected and of known and relatively high quality. The designers were well aware that they could have made a "better" system with more information, but they chose the more challenging route of restricting themselves to what was available. As some of the far more expensive competing systems have begun to show their weaknesses, I trust the underlying intellectual elegance of DRGs will be better understood and appreciated.

We must consider conflicting reporting requirements. The JCAHO now has indicator data sets and is asking hospitals to collect new information. Monitors are also coming from other directions and ask for similar kinds of information. I think an effort to develop a small, simple, and high quality data set for clinical evaluation purposes is essential.

Finally, we do not know very much about using aggregate data. I have worked with the Connecticut Hospital Association on a project to employ Statewide data on a voluntary basis to help all hospitals in their QA activities. There are few road maps the

various committees can follow to help make large aggregate data bases useful for local quality efforts. We are now well into an era when researchers are doing remarkable things with data aggregation and data use. The more practical question is how to aggregate and display data so institutions can better understand themselves.

Research: Other Needs

Practical tools for quality improvement are by no means the only need we have to help us improve our institutions. Whether it is called efficacy or outcomes, we need to know more about what works and what does not work. There has been much attention in the press recently to the fact that several famous individuals have been treated for prostate cancer. Several of them fall into age groups that, in another country, would have led to a treatment protocol which called only for watchful waiting. We tend to treat in this country; we tend to treat aggressively, and we tend to treat at high cost. I can do a great deal to ensure that my health center is screening for prostate cancer, entering patients into protocols, and administering drugs. But I cannot, in an individual institution, answer the question of whether we are benefitting men over a given age when we treat the disease.

Having said all this, let me go back to the beginning and say that I do not think quality research should focus only on what we are doing and how well we are doing it. Like the drunk in the old story, that puts us in the position of looking for the keys under the light when we ought to know they are not there.

We work in a troubled health care system. I know some very nice and very hard working people in my town who have no health insurance and live in terror because of it. We have to fix this system soon, and we have to ask research questions that help the people who want to fix it. I would expect that anyone here could, if called upon, stand up and tell us in some detail about small area variation in medical practice and what it proves about the tendency of surgeons to do surgery. I also expect that almost all of you think of this as a tool to measure institutional or physician performance.

Small area variation is, interestingly enough, also a way to look at social need; it is possible to examine hospital discharges in New York City by zip code. What you see is wide variations in, for example, hospitalization rates of children. These variations come not from physician practice or hospital greed but from the lack of medical care and even from the lack of adequate housing. Acute respiratory diseases—including acute asthma—exacerbations of diabetes, and dehydration secondary to diarrhea are the markers of an inadequate health care system. Small area variation can tell us in detail just how inadequate it is in parts of New York.

Aggregate data bases tell us an unhappy story that we have already heard but neither loudly nor clearly enough: problems with quality once patients are inside an institution are not the most severe problems we face. Institutions have to keep improving, but our entire health care system must continue to improve as well.

A Perspective on Quality Assurance Research

Sheldon Greenfield, M.D.

The purpose of this presentation is to provide an overview of quality assurance/quality improvement research. At the outset, it is important to distinguish effectiveness from quality. Many people assume they are the same, but there is a critical difference: effectiveness is an essential part of quality of care, but it is not synonymous with quality of care. Even if we know what is effective and what should be done, it does not mean it will be done well.

Quality of care assessments go well beyond effectiveness in an attempt to explain how things were done. In the case of a procedure, for example, was it done well; was postoperative care good; was interpersonal care good; was care efficient; and so forth? Quality of care differs from effectiveness, although the two overlap. Most people working in this field are doing effectiveness research. Those interested in quality get less attention. It is much easier to get a paper published, for example, on the effectiveness of a drug or procedure than on a quality of care method or quality of care findings.

This was a very timely conference for multiple reasons: one, the resurgent interest in quality of care research; two, better research methods; three, recognition of the need for a comprehensive approach to quality of care; four, vastly improved information technologies; five, recognition of the need to change behaviors; and six, awareness of the need for approaches that are sensitive to the context of care—that is, the setting where care is rendered.

We have developed increasingly sophisticated methods and approaches in the quality of care field. There has been an explosion of research in the field of outcomes, not only to improve measures of outcome but, more importantly, to appreciate what goes into a good outcomes study. There also has been an enormous amount of work on guidelines, although not so much on the "downstream effect" —that is, what happens to them after they are released. The research done at RAND and by David Eddy and many others on guideline development has been a key advance.

Dr. Greenfield is a Senior Scientist, The Health Institute, New England Medical Center.

Management Information Systems

As chairman of the Agency for Health Care Policy and Research's (AHCPR's) Health Care Technology Study Section, I have been involved in the review of proposals for many of the major management information systems in this country. For the most part they were funded in isolation or certainly without having a quality of care purpose specified. There have been many advances in national databases, but the question remains: can medical information systems be customized to provide the kind of information on quality that we need so much? Some of the most important advances have come through the work of William Tierney and Clement McDonald's group at the University of Indiana. They created a medical information system that tells you more than whether something was done or not (such as a claim), but actually reveals the result, so you can stage the patient, guide care, and judge outcomes at some later time.

In our Patient Outcomes Research Team (PORT) study on diabetes—which is taking place at the University of Indiana, the Group Health Cooperative in Seattle, and the Tufts Associated Health Plan in Boston—we are attempting to minimize our dependence on the medical record. Instead, we are relying on the administrative data base and direct information from the patient. I believe the medical information systems to support these activities, with their potential to customize for quality, have been a major advancement.

Behavioral Change

It is now recognized that although we can assess something, that does not necessarily mean we can improve it. All the cost containment literature has now confirmed what we already knew: professionals do not change easily. They lack motivation to

change, and a new approach to behavior change among professionals is needed.

Finally, there is the issue of context sensitivity. Those of us who have gone back and forth between different settings to do quality of care research have a better sense of the differences that exist, not only in the data that are available, but also the purposes, motives, and other factors that affect settings in which people work. These factors must be taken into account; if you take measures off the shelf that work in one place, it is not surprising that they do not work in another. There is now a finer appreciation for sensitivity to context and the need to tailor measures and other ideas to individual situations. This may run counter to what many researchers and innovators would like to see, because when they put forth a method, they assume it can be used universally; that is not necessarily the case.

Quality of Care Research

These advances make possible some quality improvement activities that many of us never imagined at an earlier time. I will cite several studies, a few of which are related to our own work and some that represent the work of others. They reflect the incredible advances in quality of care research and hint at some developments that are on the horizon.

First is the study by O'Connor, Plume, Olmstead, and colleagues (1991) on the mortality outcomes of procedures, specifically mortality following coronary artery bypass graft (CABG) surgery. Crude hospital mortality rates between surgeons were adjusted using multiple variables, and the differences remained. This was also done for different medical centers, with the same result. The investigators came to the conclusion that they had chosen those variables which themselves could cause death, independent of the quality of care. They were able to select these variables because there are more than 20,000 published studies of CABG.

O'Connor and colleagues took things a step further and put all the variables in multivariate equations; then they tested the value of each variable as it predicted the outcomes to decide whether the variable could be used as a confounder. After all the confounding variables—that is, severity, case mix, type of admission, age, sociodemographics, and so forth—had been accounted for, it was possible to conclude that quality of care might be the culprit. With respect to mortality following surgery, this is a model study for choosing the right variables, doing the right analysis, putting it in the right context, not overinterpreting the information, and making it plausible to readers.

Another example is the so called "Six Hospital Study" in which I was a participant. Three hospitals in Boston (Brigham and Women's Hospital, Massachusetts General Hospital, and the New England Medical Center) and three hospitals in California (University of California, Los Angeles; University of California, San Francisco; and Stanford) participated in the study. An early report of this study appeared in the *Journal of the American Medical Association* (JAMA) (Cleary, Greenfield, Mulley, and others, 1991). We selected six common conditions and looked at patient outcomes for 3 months to 1 year following hospital admission using functional and health status data based on Paul Cleary's and John Ware's measures. Then we went back to the charts to look for case-mix and hospital process, volume, and complication measures.

A brief look at the results of this study—in particular, the substudy on total hip replacement—indicates how this information might be used in a quality of care study. Patients' physical functioning in four of the six hospitals at 1 year following total hip replacement for arthritis was one of the outcome dimensions. Physical function scores ranged from 0 to 100. After first controlling for age, education, marital status, and sex, the scores were 75, 78, 74, and 68 at these hospitals. Next we used another model in which we added baseline functional status. In the third model, we added comorbid disease—that is, all the remaining conditions affecting the patient were summarized into a single number. The differences appeared as we changed models. For example, originally there was a statistically significant and important clinical difference between two of the hospitals. As we put comorbidity and baseline functional status into the models, the difference got smaller and then disappeared. This demonstrated that we can build models to show what difference quality of care might make with respect to recovery and functional status but not to mortality. We must take care not to attribute some of these differences to quality when in fact they result from other factors.

As in the O'Connor study each of these variables was related separately to outcome, both bivariately and multivariately. The hospitals differed widely on these factors: in one community hospital, 50 percent of the patients had major levels of comorbid

disease. In a West Coast referral hospital, 19 percent of the patients had major comorbid disease. This study showed that we can use functional outcomes of hospitalization as one measure for continuous quality improvement (CQI).

Gene Nelson and Dave Buchanan at the Hospital Corporation of America are conducting an innovative study on acute myocardial infarction. They are adding a CQI model to the process and collecting outcomes data at two different times. They are looking at administrative processes as well as physician decisionmaking, for example, the time it took the patient to get from the emergency room to the coronary care unit.

In the Medical Outcomes Study, we examined four factors (system, specialty, utilization, and interpersonal care) in relation to health status and quality of life. The whole analysis depended on how well the quality of life measures reflected quality of care. The study had a cross-sectional part in which we went to the offices of physicians and collected information from over 20,000 patients and their doctors. We followed about 10 percent of these patients over a period of 4 years. The study was conducted in three major cities, and we included five systems of care involving more than 500 providers.

There was great interest in whether we could develop the right measurements for use in outpatient settings to assess quality of care. If we lacked good measures of outcome and case mix, we would be totally dependent on the medical record—a situation some of us feel is less than ideal. Therefore, we developed simple clinical severity levels. We compared these severity levels with functional status to see if they had a relationship that would ground the functional status measures in reality. Such a relationship would mean that, on average, if a person is sicker by our clinical standards, they will report themselves as sicker. In addition, if there is a relationship, it also indicates that the clinical measures are working.

We were not looking for a perfect relationship because then health status would not add anything to clinical severity or vice versa. This can be seen in our diabetes data; as clinical severity increases, general health perception, physical function, and role function go down markedly, yet there is a wide standard deviation. Between two people with the same disease level, one has a very good functional status and the other is down on the scale, suggesting a major role for medical care. We have done this for a series of diseases. I want to emphasize that one of the validity issues for measurement of health status or quality of life has to do with grounding the measure in clinical reality and measuring its ability to predict clinical outcomes.

Armed with these measures, we can do some interesting things. As reported in the March 25 edition of JAMA (Kravitz, Greenfield, Rogers, and others, 1992; Greenfield, Nelson, Manning, and others, 1992), we examined utilization in these systems: health maintenance organizations (HMOs), multispecialty group prepaid, solo or single specialty group pre-paid, multi-specialty group fee-for-service, and finally, solo single specialty fee-for-service (traditional) practices. We looked at multiple parameters of utilization and found big differences in utilization between systems. There were significant differences in case mix, and we adjusted for about 20 indicators of case mix, including health status and clinical severity. Even after adjustments, hospitalizations by the solo fee-for-service practices were still 41 percent higher compared with HMOs. If we have done this right, we have developed utilization variables that will allow us to look downstream and say that the patients of these physicians are or are not getting more for their money than the patients of other physicians. This method can be used as an independent input variable.

The Massachusetts Peer Review Organization (PRO), in conjunction with the Cleveland Clinic, Lahey Clinic, and Ochsner Clinic, is beginning a similar study on quality of care for diabetes and hypertension. They will look at various outcome-dependent measures and compare them with the regular PRO external review and with claims data. This area of practice-based outcomes and quality of care research is very promising.

At the Harvard Community Health Plan, we are combining outcomes and guidelines in the same study. The doctors involved in this study went through a guideline program; the objective was to examine the degree to which they used the guideline, how they used it, and whether it affected outcomes. For example, if the care was too parsimonious, did that have a negative effect on quality as reflected by outcome?

After the doctors finished the course, we used the dyspepsia guideline in treating patients and followed the patients to obtain outcomes data. We collected information 3 to 4 months after the patients appeared for treatment, so we had good outpatient,

disease-specific data. The levels of SF-36 outcomes matched other national data for outcomes, so we knew the parameters were good in terms of our collection of outcomes data. We examined adherence to guidelines and could see how often things were done (for example, how often patients were referred to gastroenterology). This gave us a sense of relating process of care to outcomes by following guidelines. This serves several purposes: one, it shows the value of the guidelines, and two, using information on process of care provides insight that outcomes alone cannot furnish. This, along with CQI, provides a mechanism for the simultaneous use of outcomes and guidelines.

Conclusion

There was a time when we despaired of using outcomes to assess quality because outcomes were considered dangerous, unpredictable, and beyond our control. Some of the barriers to using outcomes are being conquered. If we can deal with these barriers, ultimately we will be able to develop outcome standards that are not muddled by other factors and can give us an idea of whether quality of care was good or bad.

In theory, for every disease and for every outcome, there are certain processes that we carry out and there are certain confounders. Some say this is too complicated, and we can never measure it. But our colleagues at the National Institutes of Health and in some other places around the world are investing a few billion dollars into mapping the genome. Maybe in 15 years we can come up with outcome models for 20 major conditions, outpatient and inpatient, and be able to make accurate assessments of quality using these outcomes.

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Quality Improvement/Quality Assurance Taxonomy: A Framework

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Quality Improvement and Health Care Reform

A report by the National Academy of Science's Institute of Medicine (Lohr, 1990) confirmed what few policymakers acknowledge: poor quality of health care is a major problem in the United States. After 2 years of reviewing scientific papers, conducting nationwide hearings, and visiting both health care providers and patients, the Institute of Medicine cited widespread overuse of expensive invasive technology, underuse of inexpensive "caring" services, and error-prone implementation of care that harms patients and wastes money (Lohr, 1990; Palmer, 1991).

Poor quality often increases the cost of care in the long run. For instance, delays in making diagnoses or in starting treatment permit a patient's health to deteriorate until the severity of illness and its complications make treatment far more expensive and less likely to succeed. Outright errors in diagnosis and treatment waste resources and may even harm patients so that their injuries require further expensive treatment (Johnson, Brennan, Newhouse, and others, 1992; Reynolds, Rizzo, and Gonzales, 1987). Failure to design and operate safe, timely, and efficient systems for implementing patient care can cause expensive errors and wasted resources (Berwick, 1989). Therefore, improving quality of decisionmaking and implementation for health care is an essential component of any cost control program. The need to control costs is the force driving initiatives for health care reform. By implication, then, quality improvement (QI) is a key ingredient of a reformed health care system.

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This report is being published at a critical time: health care reform at last is back on the public agenda because costs are accelerating, and Americans are losing access to the benefits of health care. In reforming our health care system, we should build the means for QI into the design. This charge presents planners with many challenging questions that can be answered only through research. To organize our thinking about research on quality of care, we need a model for health care delivery.

In the last half of the 20th century, not just one, but three conceptual models for the health care system have emerged: the professional, bureaucratic, and industrial models. The professional model exists primarily as a means for physicians (and subsequently other health care professionals) to deal with professional control of and responsibility for quality of care, but it also contains assumptions about the production and financing of health services. The bureaucratic and industrial models present rival schemes for the production and financing of health services, but they also contain assumptions about control of and responsibility for quality of care. Each model is used by its own adherents to advocate and evaluate policies for health care. These protagonists seldom acknowledge explicitly the model behind their arguments, a situation that obscures the real issues in many health care policy debates.

We must understand these different models in order to interpret successes and failures of past efforts to assure or improve quality. This is a key step in planning for quality in a reformed health care system. The shape of that plan will set the QI research and development agenda. I will review the three models and their implications for strategies targeted to quality, discuss the contributions made by quality assurance (QA), and explore the promise of continuous quality improvement (CQI)/total quality management (TQM). This review will prepare the way for the discussion of a research agenda.

Professional Model

Freidson defines a profession as a group of workers who control their own work (Freidson, 1970; Freidson and Rhea, 1963). Physicians control their work in various ways. First, a physician has special expertise that the patient wants but does not have; therefore, the patient is in a relatively dependent position, vulnerable to exploitation (Pellegrino, 1987). Members of the medical profession control entrance to their own ranks. Admission to the profession is obtained by demonstrating acquisition of special expertise (Freidson, 1970). This expertise is not a commercial property; it is obtained not by purchase but by fulfilling requirements defined by leaders in the profession, namely attendance at an approved medical school and passage of a qualifying examination (Pellegrino, 1987). Third, control of medical practice is exercised by professional colleagues. On graduating from medical school, new physicians mark their entrance into the collegium by taking an oath to accept the responsibilities of the profession (Pellegrino, 1987). These responsibilities include a fiduciary relationship with the patient and a responsibility shared with colleagues for maintaining professional standards. Professional standards are evaluated by respected peers (Freidson, 1970). The profession is "a company of equals," but respect is accorded to colleagues in proportion to their expertise (Freidson and Rhea, 1963; Goss, Battistella, Colombotos, and others, 1977; Hall, 1946). Despite advice from peers, each physician retains individual responsibility for making decisions on the care for his or her own patients.

The primary professional mechanism for quality control is the personal responsibility and integrity of each physician (Freidson and Rhea, 1963; Pellegrino, 1987). This personal responsibility is supplemented by the second mechanism described above, voluntary collegial activities among physicians (Goss, 1963). Professional colleagues help one another to provide good quality care and certify quality or award credentials to demonstrate accountability to the public (Roberts, Coale, and Redman, 1987). Within the medical staff of a hospital or group practice, collegial means to promote quality are case conferences, review of work by peers, and lectures on advances in medical knowledge (Roberts, Coale, and Redman, 1987). These are internal mechanisms.

There are also external mechanisms for promoting quality. Examples of these that take a collegial form include the disciplinary and educational activities of State medical and specialty societies. Specialty boards, composed of physicians certified in a given specialty, also accredit postgraduate training programs and certify competence for specialty practice by examination of applicants on completion of training. In hospitals, there are requirements of the physician-dominated Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) (Roberts, Coale, and Redman, 1987)[1] for medical staff review committees. Among these are physician-credentialing committees, which may require specialty training for a physician to have privileges for a particular type of practice in the hospital.

The third mechanism for ensuring quality is also external. State governments, as guardians of the public interest, restrict licensure to those with proven expertise in medicine (Cohen, 1974; Relman, 1985). Since State government officials, like patients, lack special expertise, they turn to physicians to help them distinguish competence from incompetence. Medical schools, run by physicians and accredited by the physician-dominated Association of American Medical Colleges, train entrants to the profession. The National Board of Medical Examiners, composed of physicians, provides examinations that State governments accept as demonstrating competence for licensure.

Licensing also serves physicians' interests. It gives them a monopoly and provides physician-dominated State licensing boards with the means to restrict the numbers of potential competitors permitted to enter practice. Originally, a State license to practice medicine was valid for a lifetime. However, the State licensing board can withdraw the license to practice from a physician found to be impaired or incompetent or to have violated professional ethics. In all these ways, as Freidson (1970) notes, members of the profession control access to and continuance in the profession.

The Joint Commission on Accreditation of Hospitals (JCAH) was founded in 1952; in 1987 it changed its name to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Hereafter in this text, the name of this organization that applied at the time period being discussed will be used.

Bureaucratic Model: Health Care as Administering Benefits

By the 1960s, advances in medical science and health care were occurring so rapidly that changes in professional work became inevitable (Starr, 1982). These advances in health care technology made possible treatments that are effective but often expensive and dangerous. The pace of change has become such that knowledge acquired in training is no longer sufficient for a lifetime. Physicians who fail to learn about new developments are a danger to the public; a physician can lose competence not only through impairment, but also through failure to keep pace with changes. To cope with the explosion of knowledge, physicians increasingly specialize within a narrow domain of expertise; even so, individual physicians are hard pressed to keep up with medical research even in a relatively narrow specialty. Not surprisingly, it was during the 1960s that the proportion of physicians in single or multispecialty group practices began to grow rapidly, while the proportion of physicians in solo practice began a rapid decline. Group practice was advocated during the early 1970s as a way to promote quality through collegial support (Graham, 1972).

The organization of health services is also affected by the rapid progress in medical science. As more effective health care technologies emerge, the variety and complexity of services expand. Intensive care is provided for patients undergoing major procedures or surviving the initial stages of catastrophic illness. Continuing ambulatory care is given for chronically ill patients over long periods. Preventive care also becomes an obligation. Since the medical profession is splintered among specialties, many physicians may be needed to take care of a single patient. Furthermore, many other professionals—such as operating room technicians, medical social workers, physical therapists, nutritionists, and phlebotomists—now share in the care of patients. Many types of equipment and facilities, as well as the personnel to maintain them, are essential. With so many types of personnel working together, communication and coordination of shared responsibilities become the key to quality care. Hospitals and large group practices expand their operations to handle this increased complexity, developing internal administrative systems for care delivery.

Inevitably, new technologies also increase the cost of care. Even in the 1930s, the expense of medical technology strained the financial resources of patients. Health insurance was introduced to permit prudent persons to provide for the possibility of needing health care. By the 1960s, the cost of health care had grown so much that public opinion supported Federal and State governments taking on a role as third-party payers for health care for the poor and elderly. A new type of organization also emerged that combined the financing and production of health services: originally called prepaid group practices, these evolved into health maintenance organizations (HMOs) whose numbers grew rapidly in the 1980s.

The model initially developed for coordination and control of health care in this era was bureaucratic. Bureaucracies are large organizations employing full-time salaried workers who are hired, retained, and promoted on the basis of how well they fit performance specifications (Downs, 1967). Bureaucracy is a way to ensure an orderly flow of complex activities in a large organization. To achieve this, the bureaucracy is organized as a hierarchy; supervisors control and evaluate the work of their subordinates.

Outputs of a bureaucracy are not evaluated with reference to external markets (in terms of profit over cost of inputs) (Downs, 1967). This means that organizational strategy is not directed toward meeting customer demand. Instead, and this is a unique characteristic of bureaucracy, work is governed by the use of highly specified, publicly disclosed procedures that ensure impartial decisionmaking. These impersonal rules are used to prevent political and personal preferences from influencing the distribution of services or the career prospects of employees. Workers are governed by these impersonal rules, which they do not set. Bureaucracies that provide services apply impersonal rules to determine eligible beneficiaries. Bureaucracies that contract for delivery of services use impersonal rules to select service providers.

How the bureaucratic model operates. The participants in health care are seen differently in the bureaucratic as opposed to the professional model. Those who are cared for are not patients but beneficiaries; individual physicians are seen as providers or even as "vendors," terms that also apply to hospitals and group practices. Hospitals and prepaid group practices are thought of as institutions run by administrators. They employ many types of professional, technical, clerical, and other workers. Physicians, however, occupy a unique position. They are

not usually employed by the institution (Freidson and Rhea, 1963; Goss and others, 1977; Hall, 1946), except in staff model HMOs, yet they need the institution and its staff in order to care for patients. The institution also needs physicians, because only they can admit patients and order tests and treatments.

In this model, the public interest is still guarded by State government, but the new actors are third-party payers: State and Federal governments and private insurers (including HMOs). The payers rely on physicians to determine who should get the services that are the benefits of insurance. For government, in its role as payer, a new relationship is set up with physicians.

Hospitals and HMOs meet three conditions inherent in the definition of bureaucratic institutions: they are large, they have salaried staffs, and, until the mid-1980s, they were not subject to market forces. However, physicians' work still remains outside the bureaucratic mold. Medical sociologists such as Freidson (1970) and Mechanic (1976) honed their theories of professionalism by studying the conflict between the professional and bureaucratic models as the bureaucratization of medicine proceeded. The professional model for physicians calls for supervision of professional work by influence and advice of expert physicians, with the individual physician retaining personal responsibility (Goss, 1963; Goss and others, 1977; Mechanic, 1976; Perrow, 1965). However, for administrative issues (which are regarded as "nonprofessional"), physicians reluctantly accept bureaucratic authority (Goss, 1963; Goss and others, 1977; Perrow, 1965).

To minimize the clash between the professional and bureaucratic cultures, hospitals and HMOs usually have parallel and separate hierarchies for professionals, such as physicians and nurses, and a separate hierarchy for general administration. However, within the physician hierarchy, the professional model still applies to medical decisionmaking: individual physicians retain authority over and responsibility for the care of their own patients. Each hierarchy within the institution administers its own rules, but none has the authority to set or change the rules of the other hierarchies. Changing rules and procedures to improve quality is therefore difficult. Recommendations for change must be passed up through the ranks to the top, and negotiations for change must be conducted among the heads of hierarchies. When many suggestions for small changes converge upon busy department heads they lack time to address them. The problems that prompted suggestions for change are remote from the experience of the department head and, accordingly, get low priority. The rigidity of the parallel hierarchies in a hospital thus creates inertia.

Payment in the bureaucratic model. When health care became too expensive for the individual to pay out of pocket, health insurance was introduced to take over a function that used to be solely the business of patient and physician. Hence the term "third-party payer." A final feature of the bureaucratic model was set in place when third parties paid hospitals on a cost-plus basis, and HMO premiums and individual physicians fees were set in nonmarket conditions.

With the advent of Medicare and Medicaid in the 1960s, government became the major third-party payer. Federal health care policy influenced events outside the Medicare program; because Medicare is the single largest payer for health care, policies developed for this program are often adopted subsequently by the private sector. The Medicare and Medicaid programs forced government to be concerned with who gets services and who can provide them. As the bureaucratic model requires, the Federal Government sought impersonal rules to decide which providers could receive public payments. Government used JCAH accreditation standards to decide which hospitals were "deemed certified" as Medicare vendors (Affeldt and Walczak, 1984). In effect, JCAH requirements for internal QA thus ceased to be a voluntary professional activity and became part of a bureaucratic regulatory mechanism for excluding bad hospitals.

When bureaucracies allocate human services, they apply impersonal rules that determine eligibility for benefits rather than focusing on determining and meeting the needs of individual clients (Mechanic, 1976). Inevitably, the Medicare and State Medicaid programs applied this approach to payment for health care. Since government officers were not competent to determine eligibility for specific medical services without physician expertise, they relied upon physicians to do it. For example, physicians were viewed by policymakers as applying impersonal rules to beneficiaries to decide who should receive surgical procedures and admissions to hospitals for medical care. The beneficiary was seen as a passive recipient. Although independent office practices are not themselves bureaucracies, physicians in private practice also were

coopted for this traditional bureaucratic role—that is, certifying that beneficiaries could receive non-hospital care and authorizing payment.

Government policymakers tend not to appreciate the fact that medical decisionmaking does not follow simple impersonal rules. Rather it requires much complex branching logic, with decisions often made in the face of great uncertainty. Furthermore, medical decisions have to be based on the patient's preferences, and patients therefore must be active participants in medical decisionmaking. What is "right" will vary from one patient to another.

Strategy for quality in the bureaucratic model. In the 1970s, QA became mandatory for hospitals through two mechanisms. First, as mentioned above, JCAH accreditation had become virtually mandatory as the means for a hospital to be certified as a Medicare provider (Affeldt and Walczak, 1984). In 1974, the JCAH added to its accreditation standards the requirement that hospitals operate internal QA (Affeldt and Walczak, 1984; Roberts, Coale, and Redman, 1987). This was a radical departure from the professional model of physician autonomy. The rationale cited by the JCAH was a malpractice lawsuit in 1964 which led to the judgment that hospital trustees are ultimately responsible for the quality of care given by staff physicians (Jacobs, Christoffel, and Dixon, 1976).

The methods mandated by the JCAH to assure quality were derived from physicians' research on quality measurement but were melded with then-current industrial strategies for QA. A major activity was medical audit, later modified and renamed "patient care evaluation." This was a cyclic, quality-promoting activity focused not on individuals but on problem-solving for the entire system of delivery (Joint Commission on Accreditation of Hospitals, 1980). Similar programs were initiated by several physician-researchers during this period (Brown and Uhl, 1970; Fleisher, Brown, Zeleznik, and others, 1976; Williamson, Aronovitch, Simonson, and others, 1975) and followed the same form as the famous Shewhart cycle (Berwick, 1991).

The second form of mandatory QA was Federal legislation setting up the Professional Standards Review Organization (PSRO) program for the Medicare and Medicaid programs. The Federal Health Care Financing Administration (HCFA) contracted with PSROs, which were voluntarily formed organizations of physicians practicing in defined areas. The program evolved slowly, but at its peak involved three types of review: (1) utilization review, or case-by-case review of necessity of hospital admission and length of stay; (2) profile analysis, an analysis of hospital claims data bases to monitor patterns of practice concerning admission and length of stay; and (3) medical care evaluation, an activity analogous to the JCAH's patient care evaluation (Goran, Roberts, Kellogg, and others, 1975).

Although physician-experts promoted medical care evaluation as a means to improve quality (Sanazaro and Worth, 1978), this did not become a priority for HCFA. Congress and the Executive Branch were interested in QA as a means to control costs by reducing unnecessary procedures and days of hospital care (Health Care Financing Administration, 1980). As a result, the PSRO program became focused primarily on utilization review.

Both internal and external quality review were resisted by many physicians, who saw them as an attack on professional autonomy. External utilization review was particularly unpopular because review was no longer conducted by known peers. Even physicians who conceded a role for external review often argued that government should not concern itself with the mainstream of competent physicians but should limit itself to catching "outlier physicians" (Colcock, 1974; Haggerty, 1974).

Professional resistance to QA was bolstered because QA, when implemented within bureaucratic institutions, had little impact on quality. QA committees were unable to change institutional systems for implementing care because the impetus for change was thwarted by the inertia inherent in hospital hierarchies. As JCAH reports of the time show, many institutions did not want to change the way they worked; they preferred to resist passively by interpreting QA as compliance with JCAH requirements "on paper" rather than in reality (Roberts, Coale, and Redman, 1987).

New Industrial Model—Health Care as Corporate Enterprise

During the 1980s, public policy emphasized introducing competition in health care as a way to force providers to behave more like managers of for-profit corporations. The key distinction between for-profit corporations and bureaucracies is that the former sell their services in a competitive market whereas bureaucracies do not (Downs, 1967). The choices made by informed consumers influence

the profits and market share of a corporation and so determine corporate survival. For-profit corporations, particularly those concerned with complex technology and rapidly changing product lines, behave differently from bureaucracies because they need flexibility to survive in a competitive environment (Lawrence and Lorsch, 1967). Corporate directors delegate control of work to managers, who are charged to produce by whatever means they deem best. Managers have authority to change the production system. Product planning is done informally in interdisciplinary groups that operate by cooperation and coordination. Job performance is judged not by conformance to rule but by externally valued outputs—that is, profitability and market share.

In the industrial-model health care system the two major classes of participants adopt new roles. Patients become customers or consumers rather than beneficiaries. Physicians either are employed by provider organizations or contract with them as business partners. Provider organizations include hospitals and HMOs, as well as new types of organizations such as large vertically integrated health care plans and managed-care organizations. These organizations employ professional and technical personnel and an increasing number of managers who expand their activities into marketing the organization's services. Few physicians are now in solo practice who are paid directly by their patients.

How does the industrial model work? In the form of the industrial model as advocated by Enthoven (1980), customers choose among health care plans; they do not choose individual physicians. In the 1990s, this pattern became reality for individuals purchasing health care, since physicians tend to work with health care plans as employees or contractors. Health care plans' decisions to contract with, or to hire, retain, and promote individual physicians may be based on their contribution to the productivity of the organization. A health care plan also may negotiate with physicians to develop practice guidelines, whose goal is to ensure consistency of the health care provided by the plan (Gottlieb, Margolis, and Schoenbaum, 1990).

There is legitimate concern that the commercial incentives inherent in a competitive health care system create a conflict of interest for the physician. Most problematic are situations where physicians can profit by referring patients to diagnostic facilities or by prescribing therapeutic modalities that they own or in which they are invested. Federal regulations are expected in the near future to limit physicians' opportunities to promote use of those services in which they have a direct financial interest (American Medical Association, 1992). Conflict of interest is also present in some form in the other two models discussed here: in the fee-for-service system traditionally associated with the professional model, physicians can profit by prescribing their own services; and in a bureaucratic model where physicians are on salary, the opportunity for physicians to underprovide their own time and effort presents a conflict of interest.

Payment in the industrial model. Payers in the industrial model include self-insured business corporations acting on behalf of their employees, as well as the Federal and State governments acting for Medicare and Medicaid enrollees. If these purchasers buy directly from individual providers in fee-for-service arrangements, they generally use fiscal intermediaries or external review agencies to control costs by managing utilization of services. Alternatively, payers now take active roles as "prudent purchasers": instead of setting premiums to cover bills approved by physicians, they contract for services with health care plans, negotiating a fixed price per enrollee. Corporations, especially, often make purchasing agreements with several health care plans to offer a controlled choice of plans to their employees.

Health care plans both manage the insurance function and provide care either by employing or contracting with physician organizations. Health care plans with fixed-price contracts are at financial risk for whatever care their patients may need. This element of risk provides an incentive to control costs through efficiency in clinical and administrative management. However, health care plans may choose to control costs in ways that purchasers find undesirable, such as discouraging sicker patients from enrolling, limiting access to services, and skimping on quality. Accordingly, purchasers are increasingly interested in quality measurements that would enable them to select health care plans and negotiate contracts on quality as well as price.

Quality in the industrial model. In the industrial model the stimulus for quality comes from the need to survive in a competitive environment. Customer preferences determine the market share of each health care plan; market share and productivity determine the success of the provider organization. The effectiveness of such market mechanisms

depends upon the ability of customers to distinguish differences in quality. Consumers have limited ability to judge the quality of health care, but recent advances in quality measurement show promise of changing this situation. A variety of valid measures of quality are becoming available. As they are used by a greater number of parties, the cost of measurement becomes more supportable. These sophisticated measures of quality are difficult for the individual consumer to interpret. Large purchasers, however, can employ specialists who are understand measures of quality. In this way, governments and corporations are increasingly able to shop for value by making informed choices on quality as well as cost.

To facilitate competition on quality, some new roles are emerging for government and other external reviewers. For instance, the Agency for Health Care Policy and Research (AHCPR), by facilitating development of practice guidelines, can be seen as setting health care industry standards, somewhat like a traditional bureau of standards. Some State governments, such as Pennsylvania's, are taking an active role as consumer guides. They collect information on quality and provide it to consumers and bulk purchasers to help them make choices (Office of Technology Assessment, 1988). The JCAHO "clinical indicators" program, launched in 1986, will collect data from hospitals and feedback performance measures showing comparisons of quality of care among hospitals of a similar type. This effort is intended to facilitate QI by providing "benchmarks" that reveal the best performance currently achievable (Joint Commission on Accreditation of Healthcare Organizations, 1990). HCFA, in its "Health Care Quality Improvement Initiative," (HCFA) also plans benchmarking activities (Jencks and Wilensky, 1992).

Emergence of Continuous Quality Improvement and Total Quality Management

During the 1980s, American corporations began to revise and expand their approach to quality. QA activities were absorbed into a more comprehensive strategy for quality management. Garvin (1988) distinguished the characteristics of "strategic quality management" as follows: quality is a constant preoccupation for top leadership; quality is linked in managers' minds to profitability; quality is defined from the customer's point of view; corporations compete on quality; CQI is seen as a way to exceed competitors, not just as a means to meet rules or standards; quality management pervades all work processes.

This new approach to quality includes the concepts of CQI and TQM. It has produced startling improvements in quality in several large American corporations that manufacture complex technical products, for example, Motorola, Xerox, Ford, and the Bridgestone Tire Company (Berwick, Godfrey, and Roessner, 1990). Since health care involves much complex technology, it is not surprising that CQI and TQM are now being applied to health care. The evolution from QA to CQI/TQM is consonant with and facilitated by the emergence of the industrial model for production and financing of health care.

Quality measurement is an essential feature of the industrial model for health care. I will review the advances in quality measurement gained during the era of QA and how the best of that experience can be carried forward into the new era of QI.

Quality Assurance

Since the 1960s, QA research has produced substantial advances in quality measurement. We have advanced from identifying single instances of poor quality through case-by-case review to quality measurement for groups of cases using computerized review systems. Leaders among provider organizations use internal quality measures to maintain standards of quality. External regulators have begun to use quality measures to monitor providers in an effort to guarantee to the public that standards are maintained.

Dimensions of quality of care. Quality measurement estimates the magnitude of a desired attribute. In broad terms, the attribute we call quality of care is the propensity to benefit patients. Providing care that benefits patients is a complex enterprise requiring many different components and activities. We extrapolate our definition of quality to these subordinate activities by specifying the attributes we desire for them, known as their "key quality characteristics." Three major categories of key quality characteristics, sometimes called dimensions of quality, can be identified (Palmer, 1991):

1. Technical quality is the degree to which providers coordinate judgment, skill, and available technology to improve the health of patients (Palmer, 1991). This dimension includes both the choice of an appropriate item of care and its safe and timely performance. For invasive procedures, Brook (1989) defines appropriate care by posing the question, "Does the health benefit of a procedure exceed its risk by a sufficiently wide margin to make the procedure worth doing?" The two attributes "appropriateness" and "good performance" are captured in the phrase "doing the right things and doing them right the first time."
2. Accessibility is the ease with which health care can be reached by a beneficiary in the face of financial, geographical, organizational, cultural, and emotional barriers (Palmer, 1991).
3. Acceptability is the degree to which health care satisfies patients (Palmer, 1991).

Definitions are also needed for three related concepts that are related to quality of care: efficacy, effectiveness, and efficiency. Efficacy and effectiveness relate to the appropriateness dimension of quality (Palmer, 1976, 1991). To measure appropriateness, we test whether providers "did the right thing"—that is, whether they used medical technologies such as tests, procedures, and treatments correctly. This determination of appropriate use presumes knowledge about medical technologies and how well they work. Acquiring this knowledge is the task of technology assessment. Efficacy and effectiveness are terms used in assessing technologies. Efficacy is the probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use. Efficacy is measured under strictly controlled conditions, such as a randomized controlled trial. Effectiveness is the probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under average conditions of use. So the effectiveness of a technology depends not only on the efficacy of the technology but also on the technical quality of the performance of the average provider, because the probability of benefit to the patient will be diminished if the average provider chooses the technology inappropriately or implements it poorly.

Efficiency is a concept related to both cost and quality of care. It is defined by the degree of quality present in a given unit of health care for which a fixed amount of resources is used (Palmer, 1991). More quality bought for the same amount of resource use indicates that the care was more efficiently produced. We also can invert the concept and define efficiency in terms of the amount of resources used to produce a given unit of health care of a fixed degree of quality. Fewer resources used to create the same amount of quality indicates greater efficiency. In either case, greater efficiency means more value for money.

Quality measurement. A quality attribute cannot be observed directly because it is an abstract notion. For actual measurements, we observe quality attributes as revealed in samples of care given to patients. We infer presence of the attribute by detecting an event that would occur if the attribute were present. The instances of patient care that we observe become the sample of care used for measurement. For instance, we observe whether recovery (a desired event) occurred for a patient who received a coronary artery by-pass graft; if recovery occurred, we assume that the patient received good quality of care. All patients who experienced coronary artery by-pass grafts make up the sample used for measurement. We also can count undesired events—such as death—as evidence that the patient received poor quality of care; these are sometimes called adverse or sentinel events.

Observing a single indicator event does not permit measurement but only an isolated quality judgment. Measurement is an estimate of magnitude, a question of "how much?" To measure a quality attribute, we borrow methods from epidemiology and compute rates of occurrence of desired or undesired events. The JCAHO calls these "rate-based" indicators (Joint Commission on Accreditation of Healthcare Organizations, 1990). For instance, we count all relevant instances of care experienced by patients in the chosen sample in the denominator of the rate; these are the denominator events. For a positive indicator, we count all instances in which those patients experienced desired events in the numerator of the rate; these are the numerator events. The criteria set to define the numerator events become the units of measurement. One way for an HMO to estimate its success in providing prenatal care is to calculate the proportion of its enrollees who received satisfactory prenatal care

(the numerator events) out of all those whose pregnancies began within a 1-year period (the denominator events). The unit of measurement is 1-year's-worth of pregnancy episodes.

Measurement error. Measurement provides an estimate of an attribute of quality, but estimates always have some error. When we observe variation in a series of measurements, we interpret the differences between measurements to mean that real differences in quality exist. If our measure were error-free, this would be so. However, there may be sources other than true variations in the quality of care that account for the variation in the series of measurements; these are sources of measurement error (McAuliffe, 1979).

Error may be either systematic or random. If a measurement is reliable, the rate of random error is low, but there still may be systematic error—that is, we are measuring some attribute but not the one we want to measure. If a measure is valid, both random and systematic error are low. When we know that proposed denominator and numerator events are influenced by sources of variation other than the intended quality attribute, we try to exclude the sources of error by respecifying the measure. Alternatively, we retrospectively adjust the measurements we obtain to correct for the sources of error. In addition, we can use statistical models to predict the expected occurrence of desired (or undesired) events, while adjusting the analysis for components of variance related to factors other than differences in quality.

Major sources of error are inaccuracies in recording, coding, collecting, and transmitting data about patient care events. Other sources of error lie in the interpretation of patient care events. Most events have multiple causes; therefore, to measure the contribution of any single cause one must adjust for the contribution of others (Orav, Louis, Palmer, and Wright, 1991). It is easiest to measure performance of a whole system, which includes contributions of all individuals within it; the main source of error then is variation contributed by patients whose care is studied and the circumstances of time and place when the measurement was made. If we want to measure performance of a group of physicians, then it is a source of error to include events that are controlled even in part by the system, by patients, or by time and place when care was given. Inevitably it is more difficult to measure performance for the individual physician than for the group; sources of error in measuring performance of the individual physician include contributions to the error rate by patients, the system, and other physicians to the extent that they control the indicator events.

Measurement of performance of individual physicians is essential to one strategy for QA: the "outlier" approach. This requires finding providers who are performing much worse than others, the outliers. The motive is to either change their performance or exclude them from giving care. In looking for outliers, the reviewer wants to know "did this provider experience more undesired events (or fewer desired events) than would be expected in a group of similar providers if he or she was in the same group as all providers?" (Kritchevsky and Simmons, 1991; Orav, Louis, Palmer, and Wright, 1991). It is inherently difficult to make measurements at this level. With individual physicians, numbers of observations are harder to accumulate than for a group of physicians, and small numbers make estimates less reliable. A more complex data base is required to measure performance at the individual-physician level—for example, one must attribute each of the denominator and numerator events to an individual provider, and all other sources of error must also be linked to the individual provider.

Defining denominator events. As we have discussed, quality measurements are rates with a numerator and a denominator. Defining eligibility for the denominator group means specifying the sample of patient care events to be observed. Within that sample, all numerator events must be observed and registered. A sample for quality measurement must be specified as to the type of data used, the data source, the method for finding (indexing) the sample of cases, the period of enrollment of cases in the sample, the time window for data collection, the methods and specific instructions for data collection, and the unit of care to which the quality assessment is applied.

1. **Data type.** This refers to Donabedian's classification into structure (data about facilities, equipment, supplies, policies, and procedures); process (data about things done to or for or by patients); and outcome (those changes in patients' health status that are attributable to the care received). Data about structure are mostly used when provider organizations are the object of study. However, having a good structure for a

hospital or HMO does not reveal anything about the actual care given, only about the capacity to produce good care.

2. **Data sources.** Commonly used sources include data compiled by providers such as medical records and claims data, data contributed by patients in response to interviews and questionnaires, and data acquired in the course of a quality judgment as in surgical second opinions and in preprocedure reviews.

3. **The index for finding the sample of cases.** Cases are commonly sampled by diagnosis from a diagnostic index or from data tapes of claims that record a diagnosis for a visit or hospitalization. Sampling the correct denominator events for a measurement is a key step in creating a valid measurement; when diagnosis defines the denominator events, thoughtful specification of the diagnosis limits measurement error.

4. **The period of enrollment of the sample.** Cases are often sampled from a year's worth of data to allow for seasonal variation in the types of patients and their illnesses and in staffing arrangements.

5. **The time window for data collection.** This is the period for which care is observed for each case in the sample. It may be defined as a fixed period of time, an episode of hospitalization, or an episode of illness. Episodes have appeal as a natural unit of clinical work, but they are difficult to use because of problems in defining the beginning and end of an episode and variations in the time interval from case to case in the sample.

6. **The methods and specific instructions for data collection.** Uncontrolled variation in procedures for data collection is a major source of unreliability in quality measurements. Rigorous quality control of data at every step in recording, coding, and processing is critical for limiting measurement error.

7. **The unit of care to which the quality assessment is applied.** Most commonly, a judgment is made for each case in a sample. These case-specific judgments may then be aggregated to create a profile of performance for an individual practitioner or for a provider institution. Profiles for many physicians or hospitals can be aggregated to describe a pattern of care. In other instances, data from many cases for the same physician or hospital are pooled, and the quality judgment is applied to the pooled data.

Note that each of these data characteristics potentially contributes error to a quality measurement. It is easier to control for sources of error when more specific details attaching to case, provider of care, practice setting, and time and place of care are recorded along with the details of care given. The current trend, therefore, is to use computerized data bases for quality measurement that permit speedy analysis of a detailed matrix of information about patient care.

Defining numerator events. Once a sample of denominator events has been defined, we can address how to judge which of these events constitute good or bad care. The means for making this judgment is a criterion. A criterion specifies how to classify a denominator event in terms of the chosen key quality characteristic and thus decide whether to count the event in the numerator. Usually, a categorical judgment (good/bad) is made, although occasionally a finer gradation is used, such as inadequate, minimal, good, and excellent.

QA initially was done by peer review of individual cases. A physician who was trusted to be an arbiter of quality reviewed the data for each case and used his or her own judgment to classify the case. This is called using "implicit" judgment, or "implicit criteria," because the criteria on which the judgment is based remain concealed in the mind of the judge. Not surprisingly, as with any form of human judgment, implicit judgments are found to be unreliable; the same unit of care may be judged differently by different judges and even by the same judge on different occasions. One can improve the reliability of implicit judgments by ensuring that all judges use the same data set, by using more than one judge and aggregating judges' findings, and by directing judges to focus on particular quality characteristics. This last maneuver is called "structuring peer review."

By asking judges to explain the basis of their judgments, we arrive at the idea of "explicit criteria," in which the reason for classifying care as good or bad is defined in writing before review begins. Explicit criteria sets have become more sophisticated by the incorporation of techniques used in medical decision analysis; they now consist of algorithms with branching logic that accommodate a

variety of patient conditions. If the data on denominator events and the data needed to classify events as numerator events are in a computerized data base, the algorithm can be programmed to compute the indicator rate. The set of measurements resulting from this program can be compiled by a scoring program to yield a set of performance measurements.

Criteria may refer to a broad range of denominator events, such as all hospitalized patients. In this case, they are called "generic." When criteria refer to a single diagnostic category, procedure, health state, drug, or test, they are called specific. Criteria may be developed by deciding what should be done, what should be the outcome (prescriptive criteria), or by comparing what is done or which outcomes occur among different providers (comparative criteria). Comparative criteria are most often used with pooled outcome data, for which it is difficult to define what should be deemed good quality.

Quality measurements usually take the form of rates, a continuous variable. For any rate, it may be desirable to set some cutoff point—a standard —that determines whether action should be taken based on this finding. Standards themselves may be set prescriptively or comparatively. Minimal standards set a floor; if care falls below this level, some sanction or corrective action is required (Field and Lohr, 1990). Alternatively, a standard may be a benchmark to show the best performance achieved; this is used to spur continuous efforts to reach the level of performance at the benchmark (Field and Lohr, 1990).

A different type of standard is used for attributes that should remain within a given range so long as a procedure is under control. Standards set as a range function like a traditional industrial quality-control chart; care falling outside the range, care that is highly variable within the range, or care that is drifting directionally within the range may require investigation and action. This approach could be used for issues of over- and underutilization.

When explicit criteria are used, they cannot branch sufficiently to cover all possible patient circumstances that might affect the process or outcome of care. To branch for all circumstances, including rare ones, would make a measure too cumbersome and expensive to develop and use. A common practice is to use explicit review and then arrange implicit peer review of cases that fail to meet criteria. The peer reviewer judges whether this case has some rare circumstance, which would mean that the criterion could not or should not be met.

Peer review has been used by the Peer Review Organization (PRO) program since the 1980s for case-by-case review of each instance of care that fails generic screening criteria designed to detect adverse patient care events. The peer reviewer decides whether corrective action should be taken for the physician deemed responsible for the adverse event. In the era of quality measurement, peer review of a sample of cases can be used to test a performance-measuring tool for its inherent error. Although measurement error cannot be eliminated altogether without making the measurement instrument too expensive and unwieldy, knowing the measurement error for a given instrument is important, for it enables us to trade off between the accuracy of measurement that we want and the amount we can spend on measurement.

Process measures: Practice guidelines. Measures of technical quality that are based on process data deal with what providers should do. But how do providers know what they should do? Earlier we quoted a definition for appropriateness of care indicating that they should do what will benefit their patients. Determining what will benefit patients is the mission of clinical research. However, the traditional method for testing the benefits to be gained from medical technologies is the randomized controlled trial, which gives evidence only about the benefit to be expected from a technology when used under ideal conditions. Considerable extrapolation is needed to derive what should be done in all other conditions.

To address this problem, AHCPR now funds Patient Outcomes Research Teams (PORTs) to analyze administrative data bases and derive information about effectiveness of medical technologies —that is, the likelihood that they will benefit patients under average conditions of use. Information from this source and from traditional clinical research can be used to formulate practice guidelines for providers.

Practice guidelines are defined by the Institute of Medicine as "systematically developed statements to assist practitioner and patient decisions about appropriate care for specific clinical circumstances" (Field and Lohr, 1990). Currently, there is a major effort within the medical profession to develop guidelines for what providers should do in particular situations. AHCPR is mandated to

facilitate development of such practice guidelines (Omnibus Budget Reconciliation Act, 1989). When a practice guideline (or protocol, or clinical policy) already exists, explicit criteria for review of process data can be based on the practice guideline. When no guideline exists, writing process review criteria, in effect, defines what the guideline would have been. When a guideline exists, computerized reminders can prompt providers about the guideline when action is needed (Barnett, Winickoff, Dorsey, and others, 1978; McDonald, 1976), and computerized review criteria can be used to determine whether guidelines were followed (see Table).

Table. Contrasting guidelines and review criteria

Practice guidelines (algorithms)	Review criteria
Guide care to be given	Review care already given
Data obtained as required	Use data documenting care given
Cover all pathways	Cover main pathways
Complement clinical judgment	Cover main pathways

When one is looking back, trying to determine whether the guidelines were followed by a provider, it is necessary to apply review criteria to data about care already given (Field and Lohr, 1990). This retrospective method of review is the most commonly used. Prospective judgment of quality is used, however, in preprocedure review and surgical second opinion review. Here a judgment of appropriateness is made before care is given, so inappropriate procedures can be prevented.

Outcome measures. As large corporations have become more interested in purchasing quality health care, it has become common to draw an analogy between the notion of industrial outputs and health outcomes. A simplified diagram of an industrial production process shows inputs (raw materials) being put through a production process that results in outputs (manufactured products). The idea of "management by outputs" is based on this model; it says that quality is improved most if managers are judged by their outputs rather than by conformance to work specifications. Too often this model is applied to health care in a simplistic way that implies that sick patients are the input and healthy patients the output. This analogy is not accurate and may lead to undesirable provider and purchaser behavior. Manufacturers control outputs in part by selecting the best possible raw materials. If this thinking is applied in health care, it condones providers and purchasers who select less sick patients in order to demonstrate better outcomes. Yet excluding sicker patients from treatment defeats the purpose of health care. The analogy also significantly overestimates the amount of control that providers have over disease. Health status is determined by many factors other than medical care, including genetic makeup, environmental factors, the number and severity of exposures to disease agents, personal lifestyle, and willingness to take action in behalf of one's own health. Health care providers cannot guarantee improved health by following specifications for their work in the way that workers following specifications can determine the outputs of a production process. The parallel with industry fits better if we see health services as the output from medical providers; the quality of these services can be measured by how positively they contribute to a patient's course of health. Thus the measure of quality is change in health status attributable to the health care given, not simply patient health status after receiving care. This idea fits with the definition of quality advanced by the industrial quality expert Juran (1988), namely "quality is fitness for use": health services are of good quality to the extent that they are fit for their intended purpose of contributing to patients' health.

In measuring quality by use of outcome data, we must control for all risk factors influencing a patient's health. This approach should include adjustment for the type (case mix) and severity of the patient's illness(es), any comorbidities, and relevant environmental and psychosocial variables (Greenfield, Aronow, Elashoff, and Watanabe, 1988; Jencks and Dobson, 1987; Smith, Pine, Bailey, and others, 1991). Theoretically, all risk factors should be measured for all patients at the start of care and used to adjust the observed outcome data to create a measure of quality of care. Unfortunately, many of these factors are themselves hard to measure, and the magnitude of their contributions to health status is poorly understood.

During the 1980s, considerable progress was made in measuring case mix, case severity, and

comorbidity (Daley, Jencks, Draper, and others, 1988; Dubois, Rogers, Moxley, and Draper, 1987; Greenfield, Aronow, Elashoff, and Watanabe, 1988; Jencks and Dobson, 1987; Smith, Pine, Bailey, and others, 1991). However, most case-mix measures were developed for adjustment related to comparisons of resource use rather than for outcome prediction (Jencks and Dobson, 1987). Those measures tested for adjusting patient outcomes were designed for use in predicting mortality and are not necessarily suitable for other types of outcomes data. Adjusting adequately for risk factors remains an unsolved problem.

Outcomes data are generally used with comparative rather than prescriptive criteria. After all possible adjustments are made for risk factors other than quality of care that influence the outcome, data on outcomes for a given set of denominator events are compared among providers. To date, death and other negative outcomes have been used most often to measure quality of care. Now, however, there are good prospects for a more positive approach to quality measurement using outcomes data. There have been great advances in measuring health status in terms of how well the patient is feeling and functioning (Lohr and Ware, 1987). Substantial contributions were made by two large studies, the RAND Health Insurance Experiment (Newhouse, Manning, Morris, and others, 1981) and the Medical Outcomes Study (Tarlov, Ware, Greenfield, and others, 1989). The latter study also is producing methods for measuring health and function for specific diseases. At present, however, there is little work on case adjustment that would permit these types of data to be used in measuring quality.

The newer measures of patient health status use data collected from patients by questionnaire. Patients also can provide factual data about the services they receive (Davies and Ware, 1988). This method is particularly useful if the providers do not keep accurate data or for data not usually recorded by providers. For instance, patients can be asked how long it took to get medical care; by applying an objective criterion to an acceptable waiting time, a measure of accessibility of care is created (Mushlin and Appel, 1980). Through questionnaires, patients also can act as implicit judges of acceptability of care by rating their satisfaction with specific characteristics of care (Davies, Ware, Brook, and others, 1986). These ratings are analogous to what industry calls "measures of quality from the users' perspective." However, the patient populations served by different providers may not be uniform in the level of service that satisfies them; adjustments for patients' differing levels of demand are therefore needed when providers are compared for their ability to satisfy patients.

How can measures of quality be evaluated? Quality of care measures can be evaluated for their reliability, validity, cost, and usefulness for a designated purpose (McAuliffe, 1984). I have already discussed reliability and validity of measures in terms of sources of random and systematic error. Such errors can occur because the denominators and numerators specified for a measurement are inappropriate or because of errors in data collection or in application of criteria to the data. Measures can be tested for validity by seeing if they behave as expected in comparison with other measures applied to the same objects of measurement. For instance, we can test whether the measures of quality being evaluated correlate positively with other variables believed to predict good quality and correlate negatively with variables believed to predict poor quality.

Quality assurance in the 1970s and 1980s. During the 1970s and 1980s, quality assessments often were made without using them for quality measurement. Several types of interventions followed directly upon detection of even a single highly undesirable event. For instance, in the first three rounds of PRO contracts, a PRO that confirmed evidence of a single gross and flagrant violation of professional standards was required to begin a QI plan for the physician concerned. Of course, the physician was guaranteed due process to dispute the evidence. Other examples of action for a single violation include mild forms of sanction such as denial of payment if preprocedure review suggests that a surgical procedure is unnecessary. Rutstein suggested monitoring of "sentinel events"—truly egregious but rare events such as a maternal death—that imply a failure in quality of care (Rutstein, Berenberg, Chalmers, and others, 1976). Any such event would trigger an investigation to determine what had gone wrong. A court judgment of malpractice also leads to a punitive intervention based on a presumed single serious failure in quality of care, since the judgment implies a finding that an injury was caused by the provider's negligent departure from the prevailing standard of care.

A problem with focusing only on isolated violations is that a great deal of review time and expense is needed to uncover a single case that warrants action. It is an unpleasant activity for the reviewers because the emphasis is on assigning blame. Another disadvantage is that goals are set too low because this method implicitly defines quality as the absence of major disasters. In industry this strategy—called "quality by inspection"—is regarded as outmoded.

In addition to case-by-case review, quality measurements were in widespread use as early as the 1970s, when both the JCAH (Jacobs, Christoffel, and Dixon, 1976) and the PSRO program required hospitals to conduct internal QA (Goran, Roberts, Kellog, and others, 1975). A QA cycle required quality measurement, taking corrective action if the findings suggested this was needed, and remeasurement to determine whether the desired results had been achieved. The requirements were obviously modeled on the famous "Shewhart" cycle, promoted in industry during the 1930s (Berwick, 1991).

Four obvious problems emerged in implementing these requirements. First, measuring quality proved more difficult than had been expected. Since there were no generally accepted practice guidelines, most QA committees spent their time getting agreement on review criteria; few progressed to the QI phase. Data bases containing sufficient clinical detail and computers sufficiently powerful to process such data were seldom available to QA committees. Also, the measurements were too global and did not deal with the level of detail where systems changes could be made (Berwick, Godfrey, and Roessner, 1990).

Second, because quality measurement was so difficult and expensive, often just a single measurement was made. A single measurement, made with invalidated measures, lacked credibility to many clinicians and hospital administrators and was insufficient to persuade them that changes might be needed.

Third, clinicians and administrators in hospitals thought of QA in bureaucratic terms as a method for detecting infractions of the rules and blaming the individual responsible for the infraction. Few QA committee members understood the concept of system change as a more powerful way to improve quality for all providers. Even if they had, it is time consuming and tedious to make changes in organizations composed of separate hierarchies. This problem of inertia was not restricted to hospitals. A *Wall Street Journal* article (White, Patterson, and Ingrassia, 1992) identified separate hierarchies in the U.S. automobile industry during this same time period as a barrier to producing high-quality vehicles. Last, but not least, most physicians resisted involvement in QA, which they perceived as an administrative activity unrelated to their own work goals.

By the 1980s, PSROs had been disbanded, and the JCAH had concluded that QA requirements had not resulted in real improvements in quality in most hospitals. The JCAH therefore reformulated its QA requirements, emphasizing repeated measurement (monitoring), responsibility for QA within each department and unit, and the importance of solving problems, rather than punishing, as the approach to QI (Joint Commission on Accreditation of Hospitals, 1980).

Quality measurement also was used to a limited extent during the 1970s and 1980s as a means for external agencies to monitor quality of care. Just before it was disbanded, the PSRO program had succeeded in getting a few PSROs to analyze profiles of use of hospital bed days to study appropriateness of use (Goran, 1979). By the time PROs replaced PSROs, hospitals had incentives to reduce use of bed days because they were paid a fixed fee according to a patient's diagnosis-related group (DRG) classification and irrespective of the number of days of stay. The resulting rapid decline in lengths of stay reveals that changing hospitals' financial incentives was an effective means of changing hospital behavior in the direction desired by policymakers.

In the PRO program of the 1980s, profile and pattern analysis reemerged as a means for repeated measures of an aspect of quality. HCFA has used mortality rates adjusted for case mix and other patient factors as a means to compare quality of care among hospitals each year (Smith, Pine, Bailey, and others, 1991). In the late 1980s, the JCAH began developing a set of clinical indicators to be used for comparing quality of care among hospitals (Joint Commission on Accreditation of Healthcare Organizations, 1990). Widespread testing of these measures has now begun. Once these measures are evaluated, the JCAH will require hospitals to report their performance on these indicators and to receive feedback comparing their performance with that of other similar hospitals. The comparisons are expected to stimulate hospitals to improve in order to match the performance of their peers.

Advances in computer technology. Quality measurement by external agencies in the 1990s will be conducted on a large scale by use of data bases and computerized methods of applying quality of care criteria. The original vision of quality measurement is getting easier and cheaper to realize as powerful computers become portable and as more and more clinical data are available on computer. The PRO program has developed a Uniform Clinical Data Set (Wilensky, 1991) to permit more sophisticated algorithmic analyses of process data and more sophisticated case mix adjustments for outcomes data. The Department of Health and Human Services has announced its support for a long-term project leading to development of a computerized patient medical record (Institute of Medicine, 1991). Its use could both directly improve the delivery of care and make it easier to measure quality and manage QI.

Effectiveness of quality assurance. We can sum up the experience with QA in the 1970s and 1980s by saying that much was learned about quality measurement, but dramatic gains in quality of care did not result. Both internal and external QA was resisted by providers. Physicians, especially, clung to the professional model, which holds them accountable only to their own patients and to their immediate colleagues. A distaste for QA seemed justified because, when implemented within bureaucratic health care institutions, it had little positive effect. This shortfall should not be surprising because QA effected little change in industries with bureaucratic structures. However, other industries, learning from the example of Japanese high-technology industries, began restructuring themselves in ways that permitted astonishing gains in product quality. We will turn now to examine the movement in industry for CQI/TQM and how it has begun to energize the quality movement in health care.

Industrial Perspective on Quality

To understand the industrial perspective on quality, we need to think back to the switch in manufacturing technique from hand-made to machine-made. Hand-made goods are produced by a craftsman who makes all the parts and fits each part to the others individually. Machine-made goods are produced by many different workers, each making just one part, while other workers assemble the parts into a manufactured product. For machine-made products, parts of the same type must be interchangeable, and parts of different types must conform to precise specifications so components will fit one another without hand finishing. The production process cannot permit variation—it must produce standardized parts or it will fail. Thus manufacturers' definition of quality came to be "conformance to specifications."

A factory has many workers on its assembly line; their activities are interdependent and have to be coordinated if the work is to be productive. Therefore, industrialization introduced systems for production. A factory has many systems, one for each "production process." A system includes inputs, workers, and outputs: each worker receives inputs, processes them, and passes them on as outputs.

To design a system, managers must choose the desired outputs, secure a supply of appropriate inputs, and design a production process known to produce these outputs from the given inputs. Each worker must then be trained to operate according to the system design. One worker "hands off" work to the next in the production line. The system cannot accommodate workers interjecting their own ideas of how to do the job because that will ruin the system; workers must do just what they are told to do.

System variation and system error. Complex systems are prone to variation from one production run to another. The more complex the system, the greater the chance of variation. Since quality depends on conformance to specifications or the absence of variation, any variation from product specifications is an error. So "system error" is the amount of chance variation inherent in a system, and it is an attribute of a particular system. This kind of variation is known by several other terms: random variation, common-cause variation, or systemic variation (Berwick, 1991; Kritchevsky and Simmons, 1991; Laffel and Blumenthal, 1989; Plsek, 1990).

By measuring the performance of a system repeatedly, we can detect the level of error inherent in the system as it is designed. While error rates will vary over the short term, over the long term they remain within statistically predictable limits that are characteristic for a given system. Poorly designed systems will have high error rates.

Reducing system error by improving system design has a large effect on quality because it affects all future runs using this system. However, we cannot ever eliminate all system error because of limits on the resources that can be spent on perfecting

system design and operation. Workers cannot be blamed for errors inherent in the system; these can affect any worker no matter how competent, because they are not under the worker's control.

Failure to adhere to the system also can result in unwanted variation. Events that are not inherent parts of the intended system may cause variations (errors), which are called special-cause or extrasystemic variations.

If we measure the performance of a system repeatedly, we can infer that an extrasystemic cause is at work if the observed variation goes beyond the bounds of the usual, short-term, common cause/random variation. Extrasystemic variation tends to cluster in association with whatever is the special cause (Kritchevsky and Simmons, 1991). A special cause may be related to a person, a place, or a time. The variation will recur whenever the extrasystemic cause is at work. If the extrasystemic cause is a persistent influence, "out-of-bounds" variation will persist, or if the systemic cause is a steadily growing influence, the variation will get steadily worse. To detect a special cause, we examine the pattern of occurrence of the variation.

Extrasystemic variation occurs when one has lost control of the system (Kritchevsky and Simmons, 1991). To restore control, one needs to remove the cause of extrasystemic variation; for example, if it is an incompetent worker, he or she must either be retrained or, if recalcitrant, replaced. If a defective chemical is present in a clinical laboratory autoanalyzer, it must be replaced. Getting rid of special-cause variation can be thought of as maintaining the system through activities known as "quality control."

If the system frequently goes out of control because of workers' failures to adhere to the system, it is not robust. Managers then redesign the system to tolerate a greater range of worker competence and thus facilitate maintaining control. For instance, airline engineers redesign cockpit instruments to make pilot error less likely. This is called human engineering. Note that a system cannot be redesigned by workers within it—redesign must come from those responsible for system management.

The industrial model applied to health care: Definitions of quality. In industry, as in health care, quality is defined differently for different purposes and from different perspectives. Garvin (1984) grouped the definitions and described them as follows.

In the concept of "product-based" quality, standards define categories of quality, with more of some ingredient associated with higher quality (structure). For instance, a type of rug is graded as to quality by the number of knots per square inch. More raw materials used imply better quality, and better quality costs more. Familiar examples are the designations good, better, and "Sears best" in the well-known catalog. Customers choose the products they can afford.

For a given product, manufacturers define quality as "conformance to specifications" or "doing it right the first time" (process). More quality in manufacturing means lower cost because reworking the defective product and fixing mistakes are avoided. This is the logic behind the claim that poor quality costs money.

The TQM approach favors "user-based" definitions of quality: these state that quality consists of meeting the needs and expectations of customers. In other words, the definitions are outcome oriented.

Value-based definitions begin with an assumption of limited resources; they define quality as the best performance that one can afford to buy.

What is the relevance of these ideas to health care? Different health care products that specify levels of comfort and convenience, what Donabedian calls the amenities of care (Donabedian, 1988), have long been offered at different prices. For instance, a health insurance policy covers only a shared hospital room; a patient who desires a private room must pay more. When we consider technical quality (the coordination of knowledge, skill, and resources to improve patients' health), it is different. Most Americans reject the idea that more or less technical quality of care should be offered at different prices. It strikes at the egalitarian ideal that all lives are of equal worth and therefore equally worth saving. Instead, technical quality is viewed as a kind of public utility to be offered at one level of quality (the best!) and at one price. JCAHO standards for hospital facilities come closest to the concept of product-based quality in that they specify the equipment, facilities, and staffing of a hospital. In keeping with the "public utility" notion, they specify one level of product: an accredited facility.

It is easy to see that the manufacturer's definition of quality fits well in the delivery of health services. In producing a computed tomography (CT) scan that is interpreted and acted upon, a wound dressing change, a dietary department bed-day, or a course of intravenous therapy, good quality requires doing it right the first time. It is also true, as in industry, that doing it right the first time will cost less.

Can we push the definition into physicians' work? A physician practice guideline is a kind of specification of the right things to do. Once we have specified a practice guideline, we can design a production system to make it easy to complete the care indicated by the guideline. The production system will not force conformance with the guideline when it does not apply; it will just make it easier to follow the guideline. This production system will consist of the fewest and simplest possible sequences of activities that support consistent performance of the guideline. In order for the system to operate well, all staff of the health care facility or hospital should be trained for their part in the production system.

Designing systems to support well-standardized physician activities is clearly desirable in health care. For example, certain activities of well-child care are recommended by the American Academy of Pediatrics. In a study of eight pediatric practices (Palmer, Strain, Maurer, and Thompson, 1984), we observed that those with well-specified routines for accomplishing these activities did better at completing the prescribed course of well-child care. Physicians at the Harvard Community Health Plan have begun a comprehensive approach to this kind of system engineering. Physicians in the health care plan establish algorithmic guidelines for managing common patient conditions; then management provides the system support to enable physicians to comply with their guideline with the least possible waste, rework, and complexity (Gottlieb, Margolis, and Schoenbaum, 1990). Can we imagine extending this thinking to widespread implementation of the guidelines emerging from the AHCPR-supported panels? Why not?

User-based definitions of quality are now used in health care. Many HMOs and hospitals routinely measure patients' satisfaction with services given and seek input on the needs and expectations of enrollees and potential enrollees (Nelson, Rubin, Hays, and Meterko, 1990; Nelson, Ware, and Batalden, 1990). A user-based definition of quality is implied by programs to elicit patients' preferences in making decisions about care (Greenfield, 1988). Another example is the growing practice of collecting data on patients' outcomes after care and using this information to redirect the processes of care (Nelson, Landgraf, Hayes, and others, 1990). An especially promising aid to meeting patients' needs is the routine use of surveys of patients' functional health status. These are now available in short and easily used formats (Nelson, Ware, and Batalden, 1990; Stewart, Hayes, and Ware, 1988).

Last, value-based definitions of quality have an obvious place in health care. In the 1980s, public policy was to fix prices and control volume of services through external review. For instance, the Medicare program sets a single fixed price for a unit of hospital care or physician service. The value-based definition of quality now applies: we seek the highest quality of this unit of care given the fixed price. This is how we obtain value for money.

Quality management activities in health care. The new version of quality management brings with it a new "corporate culture" wherein all employees, professional and nonprofessional, strive for quality in their work. Top management must exert leadership to this end. New structures are required: QI activities are coordinated by a steering committee but are conducted by QI teams within units of the health care organization. The teams spin off work groups to study and solve specific problems. For most health care institutions this will require a breakdown of existing hierarchies into a more flexible and interdisciplinary style of organization.

Since quality is defined as meeting the needs and expectations of customers, a dialog must begin between customers and suppliers. Patients are obviously customers, but colleagues and coworkers to whom one supplies services also are seen as "internal customers." Managers must discover what both kinds of customers define as the key quality characteristics for performance of specific services. For example, within hospitals, managers can discover what gastroenterologists need and expect from radiologists and what nursing needs and expects from pharmacy. Also, through surveys or focus groups, health care plans can discover what their enrollees need and expect. Measuring quality characteristics and improving performance through system design, maintenance, and improvement becomes the work of the QI teams.

Introduction of a new technology or a new practice guideline should trigger a phase of quality design. For instance, when a new defibrillator is introduced, or surgeons start doing gallbladder surgery by laparoscopy, a system for safe and prompt implementation should be specified, and all staff concerned should be trained to fulfill their roles.

Performance of systems already in place must be studied to see how they are constructed and whether they are "in control," that is, whether there

is any inconsistency in the way the work is done (Berwick, 1991; Kritchevsky and Simmons, 1991; Laffel and Blumenthal, 1989). How often is valuable time in the cardiac catheterization laboratory wasted because patients are not transported from their inpatient unit on time? How does on-time performance vary? If a system is out of control—that is, performance is unstable and unpredictable—it must be brought under control. If a system is in control, its performance is measured, and if the level of performance is unacceptable, the system must be redesigned.

Redesign of systems is expensive and disruptive in the short term. Therefore, before a QI project is launched, managers must be sure that they have correctly diagnosed the problem. This is why QI emphasizes the study of causes of system errors. By probing further back into a chain of causation, we may locate a simple but powerful solution. It is particularly important to distinguish between systemic and extrasystemic causes because trying to fix a system on the basis of a wrong diagnosis can make performance worse.

In industry, misguided efforts to fix systems are called "tampering" (Plsek, 1990). It is tampering to discipline a worker for an error caused by the system—that is, to treat a systemic cause as extrasystemic. It is also tampering to change a whole system for care when one person's inability to do his or her job is the cause of poor performance—that is, treating an extrasystemic cause as if it is systemic. It is also tampering to react to random variation in system performance by changing the system. Most health care workers encounter frequent examples of each of these forms of tampering in health care organizations (Berwick, 1991). Tampering wastes effort and can add complexity to systems if extra policies and procedures are piled on in an effort to patch up inadequate systems. Increased complexity adds to costs and increases the risk of error.

Collecting and interpreting quality data: Quality management tools. Industry uses a wealth of simple but elegant tools for displaying and analyzing quality measurements and for helping workers draw upon their own rich experiences to analyze causes of problems in their work environment (Plsek, 1990). Leaders in many health care organizations are already adopting them. For instance, flow charts of a sequence of activities, checksheets, or brainstorming sessions can be used to identify problems affecting performance of a system. Pareto charts or pie charts, cause-and-effect diagrams (also called fishbone diagrams), run charts, and the "is/is not matrix" are tools used both to identify problems and to begin probing their causes. Familiar techniques such as the histogram, scattergram, control chart, bar chart, stem and leaf plots, and graphs are used for further pinpointing of causes. Many of these tools are specifically designed to help individuals with little formal analytic training to understand and interpret data.

Notice, however, that these are not themselves tools for measurement. Each industry must produce methods of measurement specific to its own work. In order to adopt TQM, health care organizations will need to build on the techniques for quality measurement developed during the era of QA in health care.

Quality management in health care: Will it be used? Since health care is now often thought of as an industry, it is not surprising that TQM as practiced among high-technology industries is being applied to health care. This movement has been encouraged by big corporations: those who adopt quality management in their own businesses are increasingly interested in controlling health care costs for their organizations. The Federal Government also has adopted policies that promote an industrial approach to health care.

Will the transfer of quality management ideas from industry to health care work at this time? Health care differs from other industries in ways that may hinder the adoption of TQM (Garvin, 1990). As I have noted, the connection between inputs and outputs in health care is not well understood; most customers are unable to judge quality, and measures of performance of most production systems are still lacking.

On the other hand, managing health care fits an industrial rather than a bureaucratic model in some important respects. Industry's emphasis on meeting customers' needs fits the professional model's emphasis on accountability to patients better than the bureaucratic view of patients as passive beneficiaries. The flexibility of industrial models of management, at least in technologically complex industries, is probably better suited to health care than the bureaucratic model of separate hierarchies of authority. Even physician-manager relationships may be easier in the industrial model if physicians see themselves as business partners of management. Physicians in private practice have always acted as a modified form of entrepreneur. The partner role is

likely to be more attractive than the ambiguous position that physicians occupy in a bureaucratic model, as subservient to administrators on administrative matters but autonomous in clinical judgment. However, autonomy in clinical judgment is an area of potential conflict in the industrial model because the industrial model seeks standardization of work whenever possible, and physicians (advisedly, to some extent) tend to resist it.

As we noted earlier, the innovators who introduced QA into health care during the 1970s molded it upon the then-prevailing industrial model. In implementation, QA was transplanted into a bureaucratic environment, which doomed it to failure. The chance that quality management will succeed in health care may be better this time around for several reasons. First, the switch from the bureaucratic to the quasi-competitive environment provides positive motivation for quality management; it is now in the provider's self-interest and must be done for survival, not merely to please an outside regulator. Second, methodology for quality measurement has advanced. Detailed, rapid, real-time assessment tools suitable for use in quality management in health care are becoming available. Third, experts from quality management in industry are bringing their skills and experience to the health care field. Fourth, physicians are motivated to improve, according to their internalized professional imperative, if they are convinced that patients' welfare is truly at stake. Credible measurement of quality can persuade physicians that improvement is required. Fifth, TQM is likely to make great improvements in the health care systems on which physicians depend to do their work. This factor may persuade physicians to "buy in."

Few doubt that quality management will apply to services (material flow, patient flow, information flow in health care). Less clear is the potential use of quality management for standardizing clinical work, then managing it to produce quality. The clinical guidelines initiative at the Harvard Community Health Plan may point the way (Gottlieb, Margolis, and Schoenbaum, 1990).

Role of External Agencies in Quality Improvement

How will external review change in the era of the industrial model? I will briefly examine how external review strategies have evolved to date. In the professional model, State governments protect the public from incompetent or unscrupulous providers through licensing entrants to the profession and disciplining or withdrawing licenses from providers who violate professional standards. This is an example of a purely regulatory approach to improving quality for the public; it fits the bureaucratic model of enforcing impersonal rules. This activity will always be needed.

A regulatory approach also was made mandatory for the PROs in their second "scope of work" (Lohr, 1990). PROs reviewed hospital records using generic screening criteria to detect adverse events. For each adverse event thus detected, a physician reviewer was required to determine whether the adverse event resulted from a "gross and flagrant," or a "substantial" violation of professional standards; these terms were strictly defined in the "scope of work." For a single gross and flagrant violation
or for five or more substantial violations, the PRO was required to initiate proceedings to sanction the physician. In other words, no action other than punishment was permitted.

With time, as accused physicians hired lawyers to defend their rights, a lengthy "due process" evolved for PRO sanction proceedings. During this process, it often emerged that a physician against whom sanctions were initiated had failed to keep up with medical advances and was following practices learned years ago that were no longer appropriate. PRO activities were amended, at the urging of the PROs themselves, to permit requiring a physician with "violations" to undertake a "QI plan" such as undergoing remedial training or obtaining consultation in future cases. In other words, the strictly bureaucratic approach was leavened with elements of a professional approach to an erring colleague. Nevertheless, PROs are perceived by most physicians as taking an entirely negative approach to quality: that of finding "bad apples" and removing them from the program.

A regulatory approach is demanded by some consumer advocacy groups. Their campaigns imply that improvement in quality is measured by numbers of license removals and of physicians sanctioned (Lohr, 1990).

When government first began to pay for health care, it also adopted a regulatory approach to the issue of unnecessary care. Physicians were required to certify that services provided were needed.

Adjudicating the need for services was viewed like any other situation in which bureaucracies administer benefits; it was a matter of applying impersonal decision rules. Violation of the rules resulted in denial of reimbursement for the service. Private third-party payers behaved similarly. As use and costs of health services grew dramatically, both public and private third-party payers redoubled their regulatory efforts, so that a bewildering number of external agencies now review providers' work in order to deny payment for unnecessary care.

Proponents of quality management attack the regulatory approach as counterproductive. Regulation violates one of Deming's principles of quality management: "drive out fear" (Walton, 1986). The regulatory approach invites providers to hide from or subvert quality measurement. At best, it only cuts the low end off the distribution curve of quality, whereas quality management can move the average level of quality to a higher level, a greater gain in quality (Berwick, 1989). Furthermore, complying with the multiplicity of external review requirements is costly. Advocates of quality management assert that the end result of a purely regulatory approach is inevitably more expensive, but care is unimproved. Many health care professionals are attracted to this argument.

External agencies and quality management. Advocates of quality management argue that QI should be an internal affair that is self-motivated, driven by the desire to attract customers. They contrast this with the bureaucratic approach of "do it because we say so." Nevertheless, we must recognize that the power of quality management in industry derives from the choices of customers who can distinguish degrees of quality in a product. The desire to please customers and increase market share will not drive QI unless customers buy the better product. High-technology companies in the United States did not adopt quality management until Japanese companies with higher-quality products entered the market and won over customers (White, Patterson, and Ingrassia, 1992). While some large hospitals and HMOs are adopting quality management wholeheartedly, it is doubtful that this drive for excellence will spread to all providers, or even persist in these initially enthusiastic organizations, if customers do not reward the better providers by giving them more business.

It is not easy for customers to choose health care on the basis of quality. Many factors enter into a decision about where to get health care. Some patients may value ease of access; to others a sense of trust and interpersonal ease are more important. Patients with a long-established relationship with a physician or hospital often resist a change, even if the provider is actually dangerous in the technical sense. A major obstacle is that limited aspects of quality are directly visible to patients; others, especially technical excellence, are not.

Federal policy and some consumer advocates have pressed for better measurement of quality and dissemination of data on quality of providers to assist consumers' choice (Office of Technology Assessment, 1988). Publication of such information is not likely to prove practical at the level of the individual physician because it is so difficult, both financially and logistically, to measure quality at that level. Measurement of quality at the level of the individual is also confounded because many physicians may be involved in any one patient's care, and in examining outcomes, it is impossible to disentangle the effects of the multiple providers. It is much easier to measure the quality of a group or of a provider organization than of an individual physician.

Another limitation to consumer choice of health care according to quality is the fact that most consumers have difficulty understanding quality measures. Even if they could understand, they are not likely to devote the time and effort required to make an informed choice when they are healthy, and a patient with urgent need for care—for example, one in imminent need of neurosurgery—is likely to be too ill and upset to go "comparison shopping" for a physician with the needed, highly specialized skills.

For these reasons, it has become common for health care shopping to be done at a more aggregate level than the individual provider and patient. Increasingly, care is given by managed-care plans such as HMOs, preferred provider organizations (PPOs), and independent practice associations (IPAs). Third parties who subsidize or pay for health insurance, including government and large corporations, limit the choice of health care plans for their beneficiaries and/or employees. These bulk purchasers contract selectively with health care plans to get care at a lower cost.

Such an arrangement is not a bargain if patients do not get value for their money. Therefore, bulk purchasers would prefer to select health care plans

on the basis of high quality. Once a purchaser has contracted for service, and particularly if a hard bargain was driven on price, the health care plan may be tempted to enhance its financial status by skimping on services and discouraging sicker patients from enrolling. Thus selective contracting ("buying right") must include ongoing and accurate measurement of quality. The purchaser needs a limited number of easy-to-understand measurements of quality that sum up the health care plan's performance.

Customer-supplier dialog. This scenario predicts that in the future employers and governments will contract for health services on the basis of value for money. In the purely competitive model, a health care plan might not be selected by the purchaser in a given year because other health care plans provide better value.

Industry recognizes that frequent changes of supplier are disruptive and ultimately counterproductive; this would apply particularly in health care, where patients may have long-term trusting relationships with their doctor or hospital. Japanese industry has adopted a solution to this problem called "keiretsu," which can be translated as cooperative links or consortia (Kelly, Port, Tree, and others, 1992). Keiretsu come in vertical and horizontal forms. A vertical keiretsu is a form of "customer-supplier" dialog. In contrast to the tough and adversarial approach to procuring services usually adopted in American industries, a keiretsu is a long-term, cooperative partnership between a supplier and purchaser in which the two collaborate to improve the quality of materials supplied. In this arrangement, measurements of quality are still needed, but they are used in negotiations between the customer and supplier.

What form will quality measurements used in customer-supplier negotiations for health care take? Obviously it is too early to know, but the new directions are becoming clearer. In January 1992, HCFA announced its intention to begin working collaboratively with provider groups through the PROs to improve quality in the Medicare program (Jencks and Wilensky, 1992). HCFA will be developing measurements of quality using data from its National Claims History File and by abstracting data from hospital records into the Uniform Clinical Data Set. HCFA intends to construct quality measurements differently than in the past. Previously, HCFA strategy was to detect poor performance outliers; in its new HCQII, HCFA will use the industrial technique of benchmarking by identifying the range of performance, focusing on the best performance, and encouraging providers to match it.

The new quality indicators being developed by JCAHO also might be used in customer-supplier negotiations concerning quality (Joint Commission on Accreditation of Healthcare Organizations, 1991). They will provide valid comparisons among hospitals on a range of indicators covering all major clinical departments.

There is a different type of assessment of quality, not truly a measurement, that could be used in customer-supplier negotiation. It is the assessment of internal efforts for QI. JCAHO is gradually revising its accreditation requirements to encourage CQI (Joint Commission on Accreditation of Healthcare Organizations, 1991). There are two industrial models for assessing internal QI efforts: one is the esteemed Malcolm Baldrige Award in the United States (Berwick, 1990); the other is the ISO 9000 certificate required for companies trading in the European Common Market (Hockman, 1991). In the future, JCAHO accreditation standards may come to resemble the criteria for these awards.

Research for Quality Improvement

Research on QA in health care began in the professional era. Some date its origin to Florence Nightingale's analysis of patterns of infection among soldiers injured in the Crimean War (Lohr and Brook, 1984). Most scholars trace QA research in the United States to Ernest Codman's studies of the "end results" of surgery in 1911 (Reverby, 1981). Led by such pioneers as Paul Lembcke, the pace of research quickened in the 1950s and 1960s (Silver, 1990). Research in QA was often funded by physician organizations seeking to maintain quality by expanding existing methods for voluntary collegial activities.

In the 1970s and 1980s, with QA mandatory within Medicare, research began to emphasize measurement on a larger scale and use it for QI. Much innovative work, including the Experimental Medical Care Review Organization program, was funded by the National Center for Health Services Research and Health Care Technology Assessment, AHCPR's predecessor (Sanazaro, Goldstein, Roberts, and others, 1972). Nonphysicians began to be involved as measurement became more sophisticated and the types of research skills needed went beyond the

usual expertise of physicians. Measures that could be used by external reviewers began to appear. During these two decades there were major advances in quality measurement but less progress in QI.

Now we are at the beginnings of the industrial era in QI. AHCPR is already funding research on outcomes and effectiveness, as well as development of practice guidelines, review criteria, and performance measures. This conference was designed to help set AHCPR's agenda for QI research. Measures are needed both for more detailed work on improving systems within organizations and also for large-scale comparisons among organizations. Research in QI is expensive. When whole organizations are the study subjects, the scale of research becomes very large, and interdisciplinary teams are usually needed. The research is complex, involving clinical data bases, computerized review systems, and feedback of data displays to influence physician behavior.

As quality of care becomes a competitive advantage, new sources of funding are emerging for QI research. Some large health care plans and managed care organizations have funded their own internal departments for research and development in quality of care. Tools for utilization review and quality measurement are sufficiently in demand that investors have even funded some research and development in this field. This creates a new dilemma, however, because business-funded measures usually are not in the public domain. Industry may underinvest in this research because the payoffs may be too distant. Government, on the other hand, has insufficient funds for some of the larger efforts needed. Perhaps the solution will lie in the horizontal form of keiretsu (Kelly, Port, Tree, and others, 1992)—that is, a research and development consortium including government, health care plans, hospital chains, managed-care organizations, universities, and research laboratories, banded together to do "precompetitive" research on QI in health care for the good of all.

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Organizational Issues and Perspectives in Quality Assurance

Ann Barry Flood, Ph.D.

Introduction

Assuring quality in health care delivery, like assessing the quality of medical treatment, requires the ability to assess the appropriateness of the care and the quality with which it was performed. As daunting as these tasks are, quality assurance (QA) attempts to go beyond them in order to change performance, either to improve it or to prevent problems from arising. Yet, as Leon Wyszewianski (1988) has pointed out, the majority of studies have focused on the methods for measuring quality—the first step—rather than the means for achieving improvement.

In this paper, QA refers to both traditional QA methods already in use, as well as those based on continuous quality improvement (CQI). We continue to talk about QA but agree with George Baker (1992) who has suggested that a better term would be quality assistance—in recognition that none of the techniques actually lives up to the concept of assuring quality but merely assists in its attainment.

This discussion draws on some of the insights and perspectives of organizational theory to address basic QA issues, particularly how to use data-based methods to improve the quality and delivery of health care. I will maintain that the boundaries between successful QA models, quality improvement (QI), and utilization review (UR) are fuzzy, and that models need to explicitly recognize their interrelationships and joint effects and causes.

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Organizational Models and Control

In academia, recognizing gradations and subtleties is a mark of a thinking person, surely a scholar. On careful examination, one finds few things that are black and white. Off campus, however, the world tends to think in terms of dichotomies (Etzioni, 1991, p. 12).

W. Richard Scott (Scott, 1987; Scott and Backman, 1990) describes organizational theory in a historical context, noting the basic types of models and arguments that have been dominant during different decades and the impact they have had on the issues identified and solutions proposed by theorists, practitioners, and policymakers.

One lesson we can take from Scott's work is to be aware of the limitations on our thinking and solutions that are imposed by the selection of basic models of the problem. Of course, these limitations are always easier to see with hindsight. For example, in the early 1970s organizational models of open systems and ecological descriptions of the rise and fall of organizations helped us understand the nature and impact of a hospital's interactions with its environment, but we still overlooked the complexity of arrangements between hospitals. Managers, on the other hand, were busily building links and connections so that, when the American Hospital Association first included questions about these links in its annual survey during the 1980s, over 75 percent of hospitals reported having such links already in place!

Another lesson is that the organizational forms are changing and evolving, necessitating that models and solutions also evolve—one might say that they need CQI. One of the most dramatic and pervasive examples of such change is the evolution of managed care arrangements in health care (some would argue that this is an alias for some forms of QA and UR). At the close of the 1970s, prepaid vs. fee-for-service modes of paying for care were associated

with three basic organizational types (Luft, 1980). Group and staff model health maintenance organizations (HMOs) treated prepaid patients exclusively and could be distinguished primarily by type of remuneration and employment. The third model, the individual practice association (IPA), covered most situations where physicians treated both fee-for-service and prepaid patients. In addition to sharing this characteristic, IPAs were very different in organization; they were generally loose conglomerations of individuals or small groups of physicians practicing in multiple sites.

Economists like Alain Enthoven (1980) helped to convince a generation of policymakers that prepaid health care was the answer to concerns about both quality assurance and cost-containment because of the incentives it forced into provider decisionmaking at the individual and group levels.

At the individual level, a physician could make decisions about treatment that were relatively free of influences related to either the physician's or patient's pocketbook. Meanwhile, for the success of the group of providers as a whole, costs had to be controlled and quality maintained to continue to attract the enrolled population. With these organizational level incentives, some of the basic hallmarks of CQI—managing the processes to minimize costs and maximize health—arose first and most successfully in basic prepaid types of health organizations. Those managed care techniques included gatekeeping, review of expensive decisions to treat prior to treatment, discharge planning, and shifts to less expensive ways to provide the service such as same-day surgery.

During the 1980s, however, some of these "truths" about the fundamental differences in incentives between prepaid and fee-for-service care evolved along with the more complex organizational relationships. By the end of the decade, not only had the basic incentive structures of prepaid and fee-for-service care evolved into myriad arrangements, new and hybrid organizational forms associated with outpatient care had developed, irrespective of serving prepaid patients. Managed care techniques, which had begun with prepaid organizations, spread throughout these hybrid organizations until their use was widespread in both prepaid and fee-for-service patient care.

Indeed, the presence of one of the basic models formerly associated with treating prepaid patients exclusively—for example, a group model HMO—no longer identified an organization as treating prepaid patients most of the time, let alone exclusively. Prepayments often had little bearing on the incentive structure actually experienced by the provider responsible for making health care decisions (Hillman, 1987; Hillman, Pauly, and Kerstein, 1989). Instead, the incentive structure actually used by an organization to remunerate its providers can turn upside down the incentives supposedly inherent in prepaid vs. fee-for-service care (Flood, Fremont, Goodrick, and others, 1991). For example, prepaid practices can pay physicians on the basis of services delivered, while fee-for-service practices can pay straight salaries to physicians, irrespective of fees generated.

Yet our theory and public policy models, including QA models, continue to assume that organizations and individual providers are responding to a single incentive structure that is determined by the simple dichotomy of prepaid or fee-for-service care. The question often overlooked, despite the complexity of current organizational arrangements, is: What happens in an organization where the physician/decisionmaker has mixed incentives or multiple types of insured patients? What happens to the care of the rest of the patients when managed care or QA techniques focus only on a subset of patients?

In a recent study of a large group practice with mixed types of insured patients, my colleagues and I tried to address these issues. Preliminary results suggested that doctors believe they treat all their patients the same, irrespective of managed care or insurance, and generally argue that they do not differentiate because it is too difficult, as well as ethically repugnant, to keep track of insurance. However, when we examined their behavior, indicated by rates of using services, we found that they apparently can and do differentiate among classes of patients (Flood, Freemont, White, and others, 1992). For example, referrals to colleagues in the same clinic were higher among prepaid patients, while rates of ancillary services were lower. When educational programs focusing on the need to reduce the use of services (sponsored by the prepaid plan but supposedly not targeted to this group of patients) were conducted and rates of service use before and after the educational effort were monitored, physicians responded most strongly in areas that did not require a significant change in their practice style. For example, they changed their prescribing habits by shifting from brand-name to

generic drugs but did not reduce the per patient rate of prescriptions. Palmer (1988) found similar results in her examination of feedback to physicians in ambulatory settings.

The third lesson from Scott's (Scott, 1987; Scott and Backman, 1990) historical review, then, is the potential for gaining new insights from applying current organizational models to the questions of when and why some methods of QA work better than others. To this end, I will review the evolution of those models as they relate to methods to achieve successful organizational performance.

Basic Organizational Model and Quality Assurance

In general, organizational forms are developed in an attempt to rationalize the process by which an organization achieves its objectives. Since the 1960s, many have argued that there are two basic types of organizational models: the bureaucratic model, which uses centralized control and authority to organize work, and the professional model, which decentralizes control and authority to the worker and depends upon professional training and peer review to control work. Although the methods differ, the models share a common goal to reduce uncertainty and control work, either in procuring customers, controlling other inputs, organizing work efficiently, carrying out appropriate activities, assuring quality, or declaring the product finished.

Because these two models differ so fundamentally in their approach to controlling and evaluating work processes, many theorists in the 1960s argued that they were inherently incompatible. Critics maintained that professionals in a bureaucratic organization would be dissatisfied, and their work would be negatively affected by bureaucratic forms of evaluation and control. There were two primary reasons that this explanation gave way to more complex models of work by professionals in health care organizations. First, professionals were not as distressed or hampered in carrying out their work as the "fundamental conflicts" might suggest. Second, the simple dichotomy of bureaucrat vs. professional was clearly inadequate to describe organizations of any type. Models of organizational theory began to concentrate instead on examining:

- Multiple dimensions of control rather than simplistic dichotomies.
- The extent to which professional values and expertise could be accommodated within organizations.
- The extent to which, in any work setting, the right way to organize depends on the task to be accomplished.

Health care organizations have always operated by using both professional and bureaucratic forms of control. Some have argued that there were two independent lines of authority, one for physicians and the other for everyone else. Georgopoulos and Mann (1962) in their exposition of work in hospitals implied that these two lines of authority acted more like a lobotomized brain rather than an integrated right and left brain in coordinating activities. But others, like Scott (1982), described three models for embedding professionals effectively into an organization: the autonomous model, where professionals retain authority to control and evaluate themselves as a group; the heteronomous model, where professionals are subject to more line-authority control; and the departmentalized model, where professionals are segregated into a department that can differ from the rest of the organization. Hospitals actually have all three forms: medical staff, nursing staff, and clinical laboratories, for example.

Describing a modern version of this argument, Scott and Backman (1990) refer to the interface of the bureaucratic and professional models in hospitals as a "macromatrix" where work is accomplished by teams, some of whose members are professionals, and where different aspects of work are subject to professional and bureaucratic types of control. [See also Burns (1989) for a description of matrix organizations in health care and Scott (1987), Shortell (1983), and Alexander and Amburgey (1987) for discussions of the "modern" look of the professional-bureaucratic partnerships in health care.]

Wyszewianski, Wheeler, and Donabedian (1982) make a similar point when they distinguish between two types of efficiency in producing health care: production efficiency, requiring efficiency in managing inputs and outputs, and clinical efficiency, requiring professional judgments about the appropriateness of clinical care and suitability of skills to carry it out.

These ideas—that control of work can be done well if the form is appropriate—suggest a relatively benevolent view of the basic process of quality control: it is a way to learn from your mistakes and

to perfect the production of care. That is, problems in the production of work are due to the system and can be controlled by better management or better strategic planning. Likewise, problems in professional decisionmaking are due to errors that are inadvertent. To prevent such errors, QA involves periodic reviews by mentor-peers who can understand the vagaries introduced by individual cases and help to identify problems that can be corrected in the future. This type of model of control assumes that quality can be assured through monitoring and correcting the system for producing health care. Perhaps these methods need to be bolstered at the individual practitioner level by getting rid of the few really "rotten eggs" but mostly by rewarding good performances and making sure bad care is embarrassing enough to be worth avoiding. Basically, the model operates on the carrot side of a carrot-stick continuum and blames the system rather than the individual.

These types of assumptions have underpinned the basic approach of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) during the 1970s and the beginning of the 1980s. Almost all hospitals were at least provisionally accredited by JCAHO, not because no serious problems were found but because the Commission believed that every organization would correct the situation when given the "forced opportunity" to do so. The Commission, and indeed the benevolent view of quality control in health care production processes, came under fire in the 1980s for "covering up" some egregious problems and for failing to ensure that reasonable improvement actually occurred or that serious problems were avoided.

These problems, plus widespread disillusionment with regulatory peer review processes such as Medicare's Professional Standards Review Organizations (PSROs) (Scott, Bies, and LaPlante, 1980), gave ascendancy to another, less benevolent model of health care production processes. The definition of QA was revised to reflect a system designed to protect against abuses, with the expectation that anyone who could get away with abusing the system for personal benefit would do so.

QA as it evolved in the 1980s had some schizophrenic assumptions in its approach as formulated in public policy: drop those namby-pamby "carrot approaches" of the 1970s. Instead give free rein to competition to solve our problems in both efficiency and quality and, at the same time, rein in abuse through monitoring everyone's behavior and using sticks such as withholding payment or levying fines when abuse is uncovered.

Before exploring these next-generation models, it is interesting to note the parallels between these earlier models of QA and peer review and the current emphasis on CQI in health care (for example, Berwick, Godfrey, and Roessner, 1991; Joint Commission on Accreditation of Healthcare Organizations, 1990). To wit, CQI involves marrying a "hard" industrial engineering approach—that is, monitoring and gathering data about the production process—to a "soft" approach featuring an organization-wide QA culture. This culture should view the workers as basically well-intentioned and the best problem-solvers, so long as they are "protected" from being blamed by administration if mistakes are found and "listened" to by someone authorized to implement their solutions.

The Failure of "Benevolent" QA Methods

Three basic theories have been put forward to explain why PSROs and "carrot approaches" to QA failed in the 1970s and 1980s: the agency theory, rational control systems in organizations, and institutional perspectives and rational myths.

The Agency Theory

Americans seem to have a hard time accepting that the problem is one of defects in the system rather than of individual rascals whom they can throw out... (Etzioni, 1991, pp. 9–10).

Agency theory, where the professional acts as the informed agent to make decisions for the patient, comes out of neoclassical economic theories about what motivates people (self-interest) juxtaposed with what the professional model of health care demands from providers (decisionmaking that is independent of financial concerns). Evidence for the failure of agency models due to self-interest on the part of the agent comes from several types of studies. The first type documents evidence of extra-high rates of utilization associated with our predominately fee-for-service system compared with those of other industrialized nations (McPherson, Strong, Epstein, and Jones, 1981). A second set of studies documents services reflecting physician-induced demand rather than demands based on the popula-

tion's health needs (Rossiter and Wilensky, 1983; Wennberg, 1985; Wennberg, Barnes, and Zubkoff, 1982). The third category examines the evidence of higher rates of utilization associated with physician self-referral—that is, patients are referred for a service that in turn provides the referring physician with a form of kickback tied to receiving referrals (Iglehart, 1991).

The solution: put into place QA systems that will counteract the natural tendency for providers to act in their own behalf instead of the patient's behalf (Dranove and White, 1987) and design QA systems to counterbalance the self-interest of the "sponsor" of the activity. For example, if the review is sponsored by an insurance group, including public insurance groups, the potential conflict of self-interest of the insurance company needs to be monitored; but this is seldom the case.

Should QA systems have QA systems to monitor their results? Medicare's Super-PRO program would appear to reflect some of this thinking, although their primary purpose is still to serve the interests of Medicare.

Based on the economic model of quality control, these incentives "inherent" in prepaid insurance should work to prevent overuse of care, but not necessarily to prevent its underuse.[1] If these incentives exist, why do some managed care plans precertify use of services and use concurrent reviews to evaluate the appropriateness of "extra" days in the hospital rather than simply monitor for underuse? Is it because physicians "forget" their self-interest? This could be due to old habits learned during medical school and residency training, to current practice styles established when they or their colleagues treated fee-for-service patients, or to pressures from other self-interested parties. On the other hand, it could be that managed-care insurers are acting in their own self-interest, irrespective of the provider's interest. As noted above, in modern health care organizations remuneration of the physician or hospital may not be consistent with the type of insurance. Instead the incentives inherent in prepaid care affect the self-interest of the managed-care plans themselves, not necessarily the providers.

[1] *Underuse is seldom invoked as a problem in American health care, except when fighting off national health insurance and the evils of rationing; its moral and economic implications deserve more attention.*

Rational Control Systems in Organizations

There is a trade-off curve between control and consensus: that is, for any given level of activation, the greater the consensus, the less need for control. Which mix is used is, of course, not without its consequences; it affects the level of alienation and of resistance, and hence the future capacity to guide (Etzioni, 1991, p. 39).

The second explanation is rooted in rational models of organizations: the way to "control work," if professional ethics and training are insufficient, is to hold workers accountable by making their work visible to others whose opinions matter. In professional work, peer review is needed because only peers can truly judge the quality of one's work. This is backed up by a potential for malpractice litigation for substandard care and, to a limited extent, by financial fines and professional reprimands for poor performance.

One assumption basic to this approach is that internal review by appropriate members of the organization is more powerful than an external review because the evaluation will be seen as legitimate, authorized, and worth caring about. In other words, one's true peers are those who understand the situation, both in terms of the work carried out within a given specialty and the idiosyncratic requirements of treating one's specific patients within the limitations of the practice setting. In contrast, if evaluations and QA activities are seen as external—that is, without an understanding of local variations in the production process and without concern for disruption of the organization caused by the QA process or its outcome—the result may be a systematic attempt by providers to ignore, game, or bypass QA or UR whenever possible.

Another assumption basic to the rational model emphasizes the power of evaluations that have consequences for the individual being evaluated. In this view, people prefer to receive a good evaluation; therefore workers will seek to improve their evaluation irrespective of whether that change actually improves the quality of their performance. Ideally, of course, the evaluations are accurate and appropriate; if not, reactivity to the performance criteria can result in an appearance of improvement in performance rather than motivating the worker to seek real QI. Or, as W. Richard Scott once paraphrased an old song: When you're not near the goal you love, you love the goal you're near.

Nonetheless, there is some evidence that providers will respond to evaluation by peers "for its own sake." For example, physicians have responded to internally imposed peer review. Dyck, Murphy, Murphy, and others (1977) found that rates of healthy tissue removal associated with appendectomy dropped, without any need to reprimand physicians, when criteria about acceptable rates were made explicit. However, physicians knew that peers were going to monitor their rates in the future with undetermined consequences.

In another study of interacting drug combinations, physicians changed their overall rates of ordering any prescription drug when the computerized system for monitoring interacting drug combinations was implemented (Cohen, Flood, Himmelberger, and others, 1980). Wennberg, Blowers, Parker, and Gittelsohn (1977) found that physicians responded as expected to external feedback that their rate of hospitalization for a particular disease was unusually high, without any compulsion except continued monitoring of performance.

Finally, the work by the Maine Medical Foundation provides many examples of how a study group of physicians, when given feedback on utilization with evidence that some physicians had unusually high rates, resulted in a reduction of the outlier rates over time (Keller, Chapin, and Soule, 1990; Keller, Soule, Wennberg, and Hanley, 1990). However, some recent evidence suggests that physician profiles showing the relative rates of services use, when divorced of any apparent consequences, appeared to have no effect on behavior (Wones, 1987).

Overall, the basic approach to QA implicit in this model is neither a completely self-serving view of actions (like the agency theory) nor a completely benevolent view of QA: workers will do the right thing if they think their work is being seen by legitimate others, but otherwise, they may not.

One reason professionals may not do the right thing in the absence of evaluation is because they think they know what to do (professionals are trained to believe that they know what the right thing is), but there are few opportunities to know what others do or learn the comparative advantage of doing something differently. While continuing medical education and reports in medical journals are supposed to fulfill this function, the level of detail is seldom sufficient to inform practitioners how they might improve their techniques or manage the situation more effectively.

Institutional Perspectives and Rational Myths

... non-rational behavior is natural; rational conduct is artificial; it must be manufactured.... [and therefore] it has a cost (Etzioni, 1991, p. 68).

Institutional theory adds back into the picture four important insights that tended to get overlooked in recent QA and QI work:

1. Some organizational behavior involves rationalizing action rather than rational action.
2. Organizations, as well as individuals, will respond to how they are evaluated, regardless of whether it improves their process or product.
3. Organizations can influence and be influenced by the environment.
4. Government is not a monolithic substitute for society; it is a set of competing institutions that have their own goals and accountability.

Meyer and Scott (1983) and Meyer, Scott, and Deal (1981) argued that it is useful to distinguish between two facets of an organization's environment: the technical and the institutional. Technical aspects of the environment emphasize the efficiency and quality of the product and reward organizations on the basis of how well their products measure up to these standards. Institutional environments, on the other hand, generally operate when these criteria are unknown or difficult to ascertain; instead they resort to evaluating the process by which the product is produced. Were the rules and standards followed? Did they do as well as their peers, organizationally or individually? Did they have approved structures in place to ensure good products?

Scott and several others (see Mick, 1990) have argued that the health care system is strongly influenced by both kinds of environments. That is, technical capacity and the ability to compete efficiently, through vertical or horizontal integration, and efficient production processes influence some aspects of organizational effectiveness. Other aspects of the environment are irrational in the sense that health care organizations must respond to them regardless of their import for quality or efficiency. Requirements for accreditation can be an example of this behavior, including those that require the form if not the function of QA or CQI systems to be in place.

More broadly, licensing, accreditation, tort law, and regulations associated with quality control abound in health care. Even when they are based on widely held beliefs—what Meyer and Rowan (1977) have labeled "rational myths"—rather than on evidence of their import for quality, they have an ability to influence organizational performance regardless of the validity of the claim.

These then are the first two insights from an institutional perspective of organizations:

1. QA can have very symbolic aspects for organizations as well as individual practitioners, particularly when its outcome affects the accreditation status or reimbursement for care for a health care organization. The old view of control was that internal review and evaluation are always better; the new view is to recognize that the most powerful and least obtrusive form of control is through beliefs (Scott and Backman, 1990).
2. The process of QA—or more public processes such as HCFA's releases of hospital death rates—can cause organizations to respond in ways that may not produce any real improvement in quality and may detract from their willingness to conduct difficult investigations of problems in quality.

Some proponents of organizational environments would have us believe that organizations are hapless victims of their environments or at best can merely react (or proact) to offset the influence of environments. Others point out the extent to which health care practitioners and health care providers can influence the shape of their regulatory environment and also their competitive market. Certainly a host of lobbyists in State and Federal governments would be surprised to learn they had no effect on the development or administration of laws and budgets affecting health care. Indeed, one of the maxims of a determined lobbyist is Yogi Berra's line: "It ain't over till it's over." Even after a law is passed, it is possible to affect its impact by influencing how it is interpreted by those administering the regulations.

The last two insights from the institutional perspective are:

3. The path between health care organizations and their environments is two-way. One of the most important "battlefields" for both sides is the struggle to define QA: What should be evaluated? Who should evaluate? With what consequences? Whose beliefs should dominate?
4. Government (one aspect of the health care organization's environment) is not a monolithic institution serving as society. Instead it is a multitiered, loosely connected set of agencies and fragile coalitions with their own obligations and domains that may be in conflict with each other or at least stand in counterpoint to each other.

So how should QA be organized to actually assure quality?

Promises, Promises: The Future for Quality Control

That, at bottom, is what this is really all about: recapturing hope. We think there is at least one way out for American health care in the 1990s, namely, for health care organizations to learn and to apply the methods of modern quality management as their primary operating strategy (Berwick, Godfrey, and Roessner, 1990, p. xvi).

Continuous quality improvement is the promise put forward for the 1990s to address the problems—real and imagined—in QA in American health care delivery. CQI is often used interchangeably with terms such as total quality management, industrial quality control, and the Deming approach. Sometimes proponents are picking up only part of the message, such as data gathering and problem solving by the interested parties. But the package, to be successful, requires implementation of all features.

Its proponents include an amalgam of researchers, industrial engineers, accrediting groups, practitioners, and industrial quality control experts. The approach requires several basic features:

- Define the quality problem in such a way that it can be addressed with systematically gathered data.
- Set up the processes—defining the problem, gathering the data, and proposing the solutions—so the right people are included. The right people are those whose production is being examined and those with the clout to carry off any proposed changes.
- Create a new kind of corporate culture about solving quality problems, which needs to pervade all levels of the organization; mistakes occur because of system problems, not because of "bad" workers. Everyone benefits from better production processes, even if only in terms of morale and pride.

The philosophical approach of CQI is similar in some ways to that of groups like the Maine Medical Foundation (MMF). Both start with the premise that wide variation in practice indicates that something is amiss—not all rates can be right, even if we do not know which rate is right—but the two groups part company in their philosophical approach to which rate is right. The MMF approach targets the outliers (usually high utilization) with the view that outlying providers should alter their performance to look more like the typical performance of their peers. The CQI approach, in contrast, argues that the outliers on the side of good quality should become the benchmark against which everyone should strive: to try to be the best, not typical. The differences ostensibly are due to stressing costly utilization in the MMF and excellent quality in the CQI. But the importance of this distinction tends to get overlooked by some proponents, with the result that better quality gets mixed up with efficiency of production. As Wyszewianski and his colleagues (1982) discuss at length, there is a difference between maximizing quality in the production process and in clinical outcomes.

Although the paradigm of CQI is new to the health industry, several efforts are underway. In 1987 a National Demonstration Project on Quality Improvement in Health Care was launched. A team from 21 health care organizations was paired with an industrial quality expert in an attempt to use CQI methods to address major problems in their organizations. Their experiences are reported by Berwick, Godfrey, and Roessner (1990). Although it is a story basically ending with successes, most of the problems tackled were far removed from clinical issues in the production of health or areas typically of concern to QA efforts.

Others, including some of the 21 organizations, are trying to tackle clinical production processes. For example, Carol Sox of Dartmouth Medical School is experimenting with industrial engineering models of cardiac surgery as a production process. Instead of defining the product as a health care service (like hospitalization or surgery), the product is health. Thus, death within a specified period of time is the "nonconforming product." After adjusting for case mix, she modeled the process using typical quality control assumptions. Without having to solve the "which level is right" problem, quality control charts simply plot standardized mortality over time. The team of workers then must judge when points appear to be sufficiently out of bounds to investigate for potential problems needing solution or for indications of extra-good performance that could become a new benchmark for other providers.

The promise of CQI to be able to address these more difficult issues exists, but CQI is not a magic solution. The most difficult issues are: How do you get people to ask the right questions? How do you get people to want to, and know how to, correct deficiencies? Are the production processes involved in producing good health services the same as those that produce good health?

Iconoclastic Challenges to Inform and Reform QA Policies

Far from being highly subject to design, far from being highly malleable, societies (and sub-societies) typically are highly resistant to change. The extent to which societies are malleable depends to a significant extent not merely or even firstly on the attributes of the controlling parts, but significantly on those of the guided units, and their relationship to the controlling overlai (Etzioni, 1991, p. 40).

Open the black box of organizations. It is one thing to design public policy for QA at a macro-level in order to avoid the pitfalls of micromanagement (a valuable goal), but it is quite another when such policy reflects our ignorance. We need more research regarding several underlying questions about the promise of CQI. For example, what are the circumstances when QA is effective in achieving desirable change? What are the negative consequences that even "good" QA can have?

Examine fundamental assumptions built into QA management and public policies. The effectiveness of CQI in health care appears to rest on two types of assumptions. The first assumes that those CQI methods successfully applied to other industries also can be applied to health. This assumption often takes on a level of faith that cannot be questioned. At some level of belief this assumption is probably necessary to get past the naysayers who would dismiss CQI without trial. However, it is important to go beyond this assumption and evaluate the circumstances when CQI can be applied successfully and when not.

The second type of assumptions equate CQI with all functions of QA in health. In particular, regulatory bodies charged with oversight of multiple

organizations are applying CQI methods without recognizing that their methods contradict the supposed wisdom of CQI itself: it will not work if you punish people on the basis of what you find—for example, withholding accreditation or payment —or if the group does not see itself as a team—for example, hospitals under the jurisdiction of a Peer Review Organization (PRO). Similarly, isolated teams in several organizations are trying to apply CQI without the cooperation or involvement of other members at the host institutions. This too contradicts some of the basic tenets of CQI to involve the entire organization and cross all aspects of production.

Some assumptions should be seriously examined, not taken for granted:

- The behavior of practitioners, but not organizations or government agencies, is motivated by self-interest.
- Any form of organizing prepaid care has the same set of incentives to motivate behavior.
- Requiring implementation of CQI through regulatory oversight from PROs or accreditation by JCAHO will have the same effect as building CQI from internal pressures.
- CQI can occur effectively in a context other than maintenance and survival of a particular organization or system of organizations. New organizational forms and new health policies, like physician payment reform—maybe even national health insurance in some guise—present new opportunities as well as new challenges to design ways to assure and improve quality. Research on QA addressing these larger issues and contexts, rather than focusing exclusively on the narrow issue of CQI, is needed.

Practice guidelines may present the biggest QA challenge of all. How much do we know about the symbolic responses to their implementation? Or the ways to convince people to change? Or even the extent to which the guidelines are based on real information instead of rational myths? Are we better off if we induce all of our hospitals to offer "the best care in the world" and start a frenzy of organizations trying to imitate the "best institutions" because we have no other way to judge whether a hospital is good except it "looks" like the good hospital? Is there even such a thing as a "good" hospital? Or are they good at some care and not others? How do you assure quality or improve the process when it crosses institutions? What do you do if you find out that quality is poor and change is unlikely?

CQI challenges the value of conducting externally imposed QA as well as using traditional forms of internal QA such as peer review. Is CQI really the most effective way to motivate providers to produce better and cheaper health care? Is it thwarted by the presence of traditional QA or oversight by regulators or accrediting bodies, even if the regulators and accreditors intend to implement CQI at an extra-organizational level?

Asking the right questions is the most important step in CQI. In this context, what is the role of individual patient preferences for outcomes or for risk-taking or even for expending resources to achieve quality? How do you use CQI to examine questions about who didn't get care but should? Or examine who got care that was more likely to do harm than good? And how do you examine the quality of prevention of health problems?

Pleasing the consumer is central to CQI. For some health services, like immunizations against epidemics or providing care for the poor, society is one of the consumers. How well can you address a population's interests as the consumer, and how do you deal with consumers who need care but cannot pay for it?

Research is needed to fully understand if and how CQI does a better job at promoting quality. Is it effective, especially considering the expenditure of resources to carry out CQI? Is it really a "package" approach or are some dimensions more necessary than others? Does it only work in some contexts? Is a supportive corporate culture helpful or necessary? If necessary, how do you promote it? For example, should the methods and culture of QA be included in medical and nursing curricula?

Conclusion

We are attempting exciting and stimulating new ways to improve the quality of health care. CQI holds much promise, not only because it has the potential to improve the quality of health care services but also because it offers the opportunity to broadly reexamine our current policies and methods and to do so in a way that engages, rather than turns off, the producers and customers. Much work needs to be done to carry off these promises and to find the limitations. If we attend to the lessons already

learned from previous attempts to assure quality and from organizational theory, perhaps that more modest goal of assisting quality can be achieved.

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Quality Assurance and Quality Improvement in the Information Age

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Introduction

The increase in "value-driven" competition among health care providers and insurers, coupled with renewed pressure on third-party payers to ensure that cost-containment initiatives do not compromise quality of care, has increased the demand for information on the quality and efficiency of care delivered in all settings. The demand for usable information is likely to escalate with the continued diffusion of quality management techniques in the health care industry. The operative term is "usable information." Most health care managers and clinicians are drowning in data, but data are not necessarily information and not all information is usable.

Usable information, in the context of both quality assurance (QA) and quality improvement (QI) activities, is timely, reliable, and actionable. It empowers managers and clinicians to: fix what goes wrong; learn from what goes right; reach increasingly higher levels of service, efficiency, and technical quality; achieve better outcomes for their "customers"; and know when they have done so.

Automated information systems and technologies can be powerful tools for producing usable information, but are we using these systems to their full potential? This paper addresses the following questions:

- How do QA and QI differ with respect to their information needs?
- To what extent can currently available information systems provide potentially usable information for QA and QI? What types of information are being used now, and how are automated information systems being used to provide that information?
- What additional types of data are needed through automated information systems if QA/QI needs for usable information are to be met in a low-cost, timely, and reliable manner?
- To what extent are information technologies being used to access, analyze, and disseminate information from single or multiple linked information systems? What industry practices facilitate or impede such efforts?
- How can emerging information technologies be used to increase the range and quality of data available through automated information systems and the options available for data linkage, processing, analysis, display, and transmission? What new technologies are needed?
- What are the pragmatic and policy issues that must be addressed to realize the potential of current and emerging information technologies to improve health care quality and efficiency?

Automated Information Systems and Quality Assurance/Quality Improvement

QA has been described by Steinwachs as involving the measurement of quality as one step in a process that "monitors quality of care indicators; conducts quality assessments where indicators suggest potential problems may exist; makes recommendations for improving care based on the assessment; and continues to monitor the problems into the future" (Shapiro, Weiner, and Steinwachs, 1989).

QI may be described as the application of scientific methods to understand and continuously improve the ability of all processes to meet the needs of customers. The principal steps in the QI process include:

- Identifying an opportunity for improvement, typically resulting from the measurement of defects in the output of a process or inefficiencies in the process itself (for example, cost, cycle time).

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- Diagnosing the root causes of defects in products or services (outputs) or inefficiencies in processes and differentiating systemic from extra-systemic causes (Kritchevesky and Simmons, 1991).
- Exploring alternative interventions to achieve improvements.
- Implementing solutions.
- Monitoring performance to hold the gains.

On the surface, the QA and QI process descriptions appear very similar, but in implementation, they generally have been quite different. This is particularly true in hospitals, where the majority of QA activities have been mandated and where QA has typically been translated into "peer review."

Several authors have described the differences between QA and QI (Andrews, 1991; Berwick, 1990; Fainter, 1991; Laffel and Blumenthal, 1989), which are summarized in the Table. These differences in customers, goals, focus, objectives, measures, actions, and other features all contribute to differing information needs.

Information Needs for QI/QA: Similarities and Differences

In health care, QI encompasses both clinical and operational processes and includes as customers all of the following: the "users" (patients and their families), "nonusers" (the population for whom an insurer or a health care delivery organization assumes responsibility), public and private payers of

Table. Quality assurance vs. quality improvement in health care institutions

Characteristic	Quality Assurance	Quality Improvement
Customers	Regulators	External: patients, enrollees, families, payers, etc. Internal: caregivers, managers, technicians, support staff, etc.
Goal	Regulatory compliance	Meet customer needs
Direction	Central coordinator or committee	Decentralized through the management line
Focus	Physician	Processes
Performance measure	External standards	Capability/need
Objective	Control	Breakthrough
Defects studied	Outliers/special causes ("extra-systemic")	Common ("systemic") and special causes
Viewpoint	Reactive	Proactive
Participants	Peers	All
Functions involved	Few—mainly physician	Many— clinician and support system
Tampering	Common	Rare
Review method	Summary	Analysis
Action taken	Recommend improvements	Implement improvements
Measurement and reporting	Ad hoc, sporadic	Routine, periodic

Source: Adapted from Berwick (1990) and Fainter (1991)

services or insurance benefits, and all of the clinical and nonclinical staff involved in direct care or operational support processes.

While QA programs have relied on data to identify problems in the quality of care provided by health care services, historically they have ignored the issue of underutilization in their service area, enrolled population, or patient base. Often this has resulted from a lack of data on the nonutilizing population. This is particularly true among fee-for-service providers who have difficulty updating and maintaining patient files, given the migration of patients among providers and geographic regions. For products or services that are population based, such as screening or immunization rates, effective QI efforts will require information on both users and nonusers of a provider's services.

Although QA activities generally have been undertaken primarily to comply with regulatory requirements, the goal of QI is to meet customer needs more effectively. Data on the needs of both external customers (enrollees and patients) and internal customers (staff working within the care process who must depend on other staff to carry out their part of the process) are crucial to QI analyses. QA departments, especially in hospitals, have tended to see the collection and use of patient preference or satisfaction data as more in the domain of planners or market researchers than QA staff and the use of staff satisfaction survey data as principally a human resource department function. QI teams, however, recognize these data as important sources of information on unmet needs and/or deficiencies in care processes.

QA activities traditionally have focused on physician decisions and actions and ultimately on identifying the poor performers and improving or removing them. QI philosophy recognizes that people work within processes and that their ability to work up to their capabilities can be limited by the constraints of those processes (Berwick, 1989). Thus, data on process capability and performance are a requirement for QI analyses.

While QI does identify individual outliers in performance, that is not its principal focus. The improvement or removal of statistical outliers yields lesser gains than does improving the process capability for all performers. Thus, the central focus of QI is on achieving breakthroughs in process performance, rather than identifying "bad apples." To improve a process, QI efforts depend not only on the outcome (or proximate outcome) measures typical of QA indicators, but also on the availability of detailed data about the inputs to the process and the steps, characteristics, and temporal relationships of the process itself.

QA activities tend to be centralized and removed from the day-to-day activities of health care organizations, while QI activities engage the efforts of all members of the organization to improve their products and services by improving the processes in which they work. The QI process includes the implementation of solutions to process problems by those who work in and manage the process. QA managers, on the other hand, may recommend solutions only, and many such recommendations are never implemented. Data on the chronology of QI process initiatives must be documented to ensure consistent data on process performance measures (such as defect rates in products or services, cycle time, and cost per cycle) that will be used to assess their effectiveness over time—a quality control function.

In summary, QA programs generally have focused on what went wrong and who was responsible, not on why things went wrong. Nor have they used benchmarking techniques to examine why those same things go right in another population, delivery setting, or care context. Providing those responsible for the quality of care with information only on what went wrong often leaves them without a clue as to how care might be improved. It is the answers to the "why" questions that can provide managers and clinicians with the information they need to improve services and care outcomes.

QI focuses on the why questions by systematically analyzing characteristics of the processes that resulted in the observed defects in care. By understanding why, how, and when these processes fail, managers can act to redesign the processes and thereby improve care for all affected patients.

Recent changes in the focus of some of the regulatory agencies, such as the Joint Commission on Accreditation of Healthcare Organization's Agenda for Change, may bring the QA and QI processes closer together. In any event, many of the defects identified through QA monitoring can provide grist for the QI process, and many of the quality measurement techniques developed for QA can be used in a QI model. The data required to support the QI process, however, are both broader in scope and deeper in detail than those used for QA.

Usefulness of Automated Information Systems

To answer questions about the quality and efficiency of health care delivery, accurate, reliable data are needed. Changes in technology and medical practices require that the data be relatively current (in some cases, concurrent) with care. In addition, the range of data collected must be expanded to determine whether differences in quality are due to differences in the population or the care process and to understand the causes of known quality problems.

A basic tool of quality management is "benchmarking." Benchmarking involves seeking out successful innovations in other settings and implementing them in one's own setting when appropriate, as well as identifying the top performers in each process area and striving to exceed their performance levels.

There is increasing interest in benchmarking among institutions, health care plans, and delivery settings (Chassin, 1991; Siu, McGlynn, Morgenstern, and others, 1991). For benchmarking to be effective, however, greater uniformity of coding practices, improved consistency in data definitions, and greater comparability in performance measures are necessary.

These factors, plus the escalating demand for data both from within and outside health care delivery settings, add urgency to calls for further development and implementation of accurate, efficient, and low-cost automated data collection, processing, and analysis techniques.

While automated information systems have been used extensively in health care to support QA monitoring and—in some settings—interventions, only recently have they been used to support formal QI initiatives.

Use of Automated Information Systems to Support QA

Traditional QA activities may be divided into two types: those that are conducted within an institution or health plan, usually to monitor its own performance relative to a care standard; and those that are conducted by or for the use of external review organizations, both to document variation in performance relative to a standard and to identify poor performers.

Internal QA reviews have generally consisted of manual audits of paper charts or, in some cases, computerized patient records or ancillary support systems such as the laboratory and the pharmacy. Reviews of individual clinicians by external accrediting agencies have usually been based on manual chart audits, while external reviews of institutions or health plans have increasingly utilized automated administrative data bases, such as the Uniform Hospital Discharge Data Set (UHDDS) and/or automated inpatient claims/billing data. A number of large insurance companies have used data from their automated medical claims data bases to evaluate physicians' practice patterns and to select cost-effective physicians for their preferred provider networks. Hospitals, health maintenance organizations (HMOs), and other employers of physicians have recently been given access to the National Practitioner Databank, a data base containing information on physicians' malpractice claims experience, to help evaluate the clinical competence of prospective employees.

Numerous studies have used automated administrative data bases to study various aspects of the quality of care provided in inpatient settings in the United States. Those that focus on access to care may also provide some insights into the quality of outpatient care received prior to admission.

Several studies have examined geographic variations in hospital admission rates for selected diagnoses or surgical procedures using UHDDS or inpatient claims data (Campion, Naessens, Leibson, and others, 1992; Chassin, Brook, Park, and others, 1986; McMahon, Wolfe, and Tedeschi, 1989; Perrin, Homer, Berwick, and others, 1989; Roos, Wennberg, and McPherson, 1988; Spitzer and Caper, 1989; Wennberg, Freeman, and Culp, 1987; Wennberg, Roos, Sola, and others, 1987). Some have used UHDDS data to examine the relationship between socioeconomic variables and either small-area variation in discharge rates (McLaughlin, Normolle, Wolfe, and others, 1989) or rates of selected procedures among patients discharged with the same diagnosis (Wenneker and Epstein, 1989; Wenneker, Epstein, and Weissman, 1990). Still others have studied late hospitalizations (Louis, Gonnella, and Zelezuik, 1988), potentially avoidable admissions (Spitzer and Caper, 1989), and early readmissions.

Other automated information systems used to assess access to care include patient registration data and birth records, which are used to study adequacy of prenatal care (Krieger, Connell, and

LoGerfo, 1992) and tumor registries for analyzing the stage of breast cancer diagnoses by hospital (Hand, Sener, Imperato, and others, 1991) and access to breast conserving surgery and radiation therapy (Lazovich, White, Thomas, and others, 1991). These two latter studies also used tumor registry data to assess adequacy of treatment and followup. Within this quality parameter, peer review organizations (PROs) use discharge abstract data to study rates of occurrence of preventable complications.

In the United States, the lack of a common patient identifier has prevented the linking of data from most administrative data bases, limiting our ability to evaluate care across settings. This makes the assessment of postdischarge treatment and followup, as well as outcomes, across diverse patient populations difficult or impossible for external reviewers.

Most externally based outcome studies in the United States have also focused on hospital discharge abstracts or inpatient claims data, particularly on hospital mortality rates. The first such studies, done by the Health Care Financing Administration (HCFA), reported crude death rates by hospital, adjusted only for age and sex. More recently, methodologies have been developed to adjust these rates for patient risk based on other claims-based data fields. Studies of risk-adjusted hospital mortality rates have still shown significant variation by hospital (Blumberg, 1988; DuBois, Brook, and Rogers, 1987; Green, Passman, and Wintfeld, 1991; Jencks, Daley, Draper, and others, 1988; Smith, Pine, Bailey, and others, 1991).

Several outcome studies found a positive relationship between surgical volume and outcome (Flood, Scott, and Ewy, 1984; Luft and Hunt, 1986; Showstack, Rosenfeld, Garnick, and others, 1987) and recommended the regionalization of certain procedures as a method to improve outcomes for these types of patients. Shortell identified characteristics of hospital markets, as well as organization and control issues that may influence outcomes (Shortell and Hughes, 1988). Chassin, Park, Lohr, and others (1989) showed that the measure of mortality used (inpatient deaths, deaths within 30 days of discharge, etc.) can affect the degree of variability among hospitals.

The Medicare data files, which may be linked through a common patient identifier, permit the measurement of postdischarge mortality among the elderly enrolled in Medicare. However, studies in other populations suffer from the inability to track postdischarge mortality via automated data bases due to the lack of common patient identifiers. Such analyses require direct followup with patients, whose identities may be held confidential by their caregivers. Even when patient data can be collected and linked, the costs are significantly higher than electronic linkage to automated death records would have been.

Numerous studies using the Canadian health care system's administrative data bases (Roos and Brazauskas, 1990; Roos, Cageorge, Austen, and others, 1985; Roos, Flowerdew, Wajda, and others, 1986; Roos, Roos, and Sharp, 1987; Roos and Sharp, 1988) have demonstrated the usefulness of a common patient identifier for linking automated data bases to identify quality problems that span health care delivery sites.

However, two innovative studies mentioned previously have demonstrated the potential for algorithmically matching patient files, based on common data fields, to assess quality of care. These include: linking patient registration data and discharge abstracts with birth records to assess prenatal care process and outcomes (Krieger and others, 1992); and linking claims data with tumor registry data to assess the appropriateness of treatments for breast cancer (Lazovich and others, 1991). In addition, an automated acquired immunodeficiency syndrome (AIDS) data base has been created in Maryland by linking discharge abstracts, inpatient billing data, death records, and community-based data to study process and outcomes of care (Hidalgo, 1990).

QA activities using automated information systems also have been undertaken within some health care organizations. In most cases, these activities have been led by academic researchers based in teaching hospitals, academic group practices, or HMOs. Quality indicators selected by the organization, rather than imposed by external regulatory agencies, have been monitored using either: individual (or combinations of) internal administrative data systems, such as automated discharge abstracts, billing systems, or ancillary support systems (for example, laboratory, radiology, and pharmacy systems); or computerized patient records (alone or in combination with internal administrative data or ancillary support systems).

Data from these internal systems usually can be linked using a common patient identifier within the institution. However, incompatible data systems and

the lack of consistent standards for data exchange sometimes limit intra-institutional linkage.

The usefulness of automated data bases within institutions for monitoring clinical quality indicators has been reported widely. Some of these internally-driven studies have monitored indicators of access to care, such as: analysis of the appropriateness of patient admissions to scarce ICU beds (Singer, Carr, Mulley, and Thibault, 1983); analysis of the appropriateness of preoperative selection of patients with curable renovascular hypertension (Cugini, Di Palma, Battisti, and others, 1991); analysis of the percent of persons with AIDS who received a trial of azidothymidine (AZT) or home care services (Coltin, Wurtman, Kuvin, and others, 1990); and analysis of compliance with well-child screening and immunization standards in an HMO (Kind, 1989).

Other indicator studies have focused on recognition and documentation of diagnoses and/or adequacy of treatment or followup, including studies of the documentation of a hypertension diagnosis and adequacy of treatment in patients with recurrent, elevated blood pressure readings (Barnett, Winickoff, Morgan, and others, 1983) and the documentation of an anemia diagnosis and appropriate treatment in children with low hemoglobin or hematocrit levels using a computerized medical record system (Coltin, Neisuler, and Lurie, 1976).

In addition to using automated information systems to retroactively monitor aspects of patient care, several studies have reported internal use of automated interventions to improve deficiencies identified through QA. However, as with QA monitoring, most QA interventions have focused on clinicians, regardless of where in the process the observed defects may have originated. Clinicians are both suppliers of medical care services to patients and customers of the organizational support systems that enable them to carry out their part of the care process. Most QA interventions focus only on the supplier role of clinicians and ignore their needs as internal customers in the process. Examples include: an HMO that used computerized medical records to generate reminders to clinicians on failures to comply with standards for diagnosis, treatment, and followup of hypertension (Barnett and others, 1983) and syphilis (Winickoff, Coltin, Fleishman, and others, 1985); three hospital emergency rooms that employed an encounter data base to monitor adherence to treatment regimens and provide feedback when deviations occur (Brand, Frazier, Clancy, and Freeman, 1980); and a psychiatric clinic that used an expert system to alert clinicians to deviations from drug treatment protocols (Bronzino, Morelli, and Goethe, 1989).

In addition to individualized patient reminders, automated information systems also have been used to generate summary practice profiles. These profiles are fed back to clinicians to encourage compliance with established standards of care (Chodroff, 1990; Douglass and Batchelor, 1989; Knight, O'Malley, and Fletcher, 1987; McAlister, Correy, Tong, and others, 1986; Sickles, 1990; Winickoff, Coltin, Morgan, and others, 1984).

Many QA interventions merely use automated feedback systems to request the retrospective repair of existing defects and to exhort clinicians to do better. This is typical of the "quality by inspection" approach and often results in inefficiency or creates frustration among clinicians, who may not have been responsible for the defects and have no means to prevent future occurrences. Some of these interventions merely add to the cost of poor quality. In contrast, automated QI interventions generally take the form of organizational changes to the process of care to facilitate prevention of defects.

Uses of Automated Information Systems to Support QI

QI efforts may focus on the quality of the output or the outcome and/or efficiency of a process. Those that focus on clinical care processes require detailed information about:

1. Inputs to the process, which may be patient or population factors such as demographics, risk factors, co-morbidities, and insurance status.
2. Steps and characteristics of the process, such as technical process actions, interpersonal factors, resource and training factors, and time dependencies.
3. Outcomes of the process, such as symptom levels, complications, laboratory test results, functional status, health behaviors, mortality, and satisfaction with care.

Generally, the detailed data required for QI are available only at the local level, which is one reason why institutional QI efforts have been internal to a given care setting. Many of the data elements required for QI are contained within automated

clinical information systems in hospitals or other organized health care settings (Glaser, 1991; Hunter and Vanderslice, 1991). Such settings generally assign a unique identifier to their patients. Computerized medical record systems and multiple administrative systems—such as automated laboratory, pharmacy, or billing systems—have been linked within institutions for QI analyses and to support interventions at the institutional level.

Another reason for the institutional focus is that QI efforts incorporate the responsibility for correcting and preventing deficiencies. While many studies have used interventions to improve performance, they are not necessarily QI studies. QI studies involve the design of interventions to prevent process failures that result in inefficiency or poor outcomes. Thus, the intervention is applied to the process, not merely the physician as supplier.

Several studies using computerized medical records have employed automated reminders to clinicians at the time of the patient encounter to proactively improve compliance with diagnosis and treatment guidelines. Examples of the use of automated information systems to alert clinicians to possible diagnosis or treatment failures in time to implement corrective measures include:

- Two studies done in a single hospital setting, one of which used a combination of laboratory test results and computerized medical records to alert physicians to life-threatening conditions based on abnormal laboratory values (Tate, Gardner, and Weaver, 1990) and another that alerted them to hospital acquired infections and the appropriateness of their treatment (Evans, Larsen, Burke, and others, 1986).

- An academic medical practice that used protocols or decision rules on a partially computerized medical record system to remind physicians of indicated actions (McDonald, 1976; McDonald, Hui, Smith, and others, 1984).

- An HMO that used computerized medical records to generate concurrent reminders to clinicians at routine prenatal visits on actions needed to comply with prenatal care guidelines (Morgan, Studney, Barnett, and Winickoff, 1978) and to generate computer alerts at all scheduled visits of high-risk patients on their flu immunization status (Barton and Schoenbaum, 1990).

Automated information systems also have been used as prospective aids in clinical decisionmaking by supplying predictive data on the likelihood of either adverse events (Blaufass and Tinker, 1988; Shabot, Leyerle, and LoBue, 1987) or successful interventions (Cugini and others, 1991). In addition, a number of studies have reported the use of office-based microcomputer systems for tracking preventive screening procedures and generating concurrent reminders to clinicians or prospective reminders to patients of the need for periodic screening tests (Fordham, McPhee, Bird, and others, 1990; Frame, 1990; Harris, O'Malley, Fletcher, and others, 1990).

Still others have linked computerized patient records to existing clinical support data bases (Gottlieb, Margolis, and Schoenbaum, 1990; Kuperman, James, Jacobsen, and Gardner, 1991) or developed their own personal computer-based information networks (Edsall, 1991) to capture detailed and time-specific data on all steps in a care process, report on process performance, support the analysis of root causes, and implement computer-based interventions.

In organizations with automated patient data systems, the ready availability of computerized data may lead managers or clinicians to focus narrowly on the uses of information technology for improving all health care processes, when a QI analysis of root causes might suggest other approaches for some types of deficiencies. Likewise, the same outcome or inefficiency defect observed in different care settings could have totally different causes. Therefore, an automated solution in one setting may have little effect in another. Local investigation and focused remedial action are necessary.

Additional data needs. Care for a given health problem often can involve multiple care settings. Therefore, institutionally based studies are limited in that they may be able to improve some of the important processes within an episode of care but only reduce some of the poor outcomes. Likewise, if the root causes of institutional process defects are found to lie in broader policy issues, such as the design of health insurance benefits or reimbursement mechanisms, local solutions are unlikely to be found. Here, interinstitutional QI studies would be needed to establish root causes. The limited implementation of computerized medical record systems currently leaves us dependent on administrative data bases to address the data needs of QI activities. Some of the more detailed administrative data bases

within institutions (for example, laboratory, radiology, and pharmacy systems) may help to compensate for the lack of computerized medical records in supporting QI activities.

The ability to link such data bases across care settings to establish both the chronology and the characteristics of a care process would greatly facilitate QI efforts. These data bases also could be augmented with patient-reported data, since detailed information on both the inputs and outcomes of clinical care processes frequently are reported inadequately in medical records and administrative data bases.

Patients long have been recognized and heavily used as a valuable source of information both on their own inputs to the care process—such as demographics, socioeconomic characteristics, attitudes, preferences, lifestyle and other behaviors, and personal and family medical history—and on various types of health outcomes such as symptom levels, functional and health status, quality of life, and satisfaction with care. More recently, studies have found that patients are a credible source of information on the clinical care process as well (Davies and Ware, 1988). A number of validated instruments now exist for measuring various aspects of patients' health status (Nelson and Berwick, 1989), as well as patient satisfaction with care (Nelson, Hays, Larson, and others, 1989; Ware, Snyder, and Wright, 1976;), and a number of electronic data bases containing these measures for different reference populations now exist. None of these, however, is currently in the public domain. The availability of such data bases for benchmarking purposes would benefit not only QI efforts, but likely would encourage convergence on a limited number of instruments and lead to the growth of additional reference population data bases.

While automated information technologies for collecting data directly from patients have existed for quite some time, they have seen limited use in patient care settings (Roizen, Coalson, Hayward, and others, 1992; Thomas, Fairbank, Pynsent, and Baker, 1989). The diffusion of these technologies into clinical practice could help not only to reduce the costs of data collection, but also to improve our ability to incorporate data on patient-identified needs and preferences into real-time clinical decisionmaking. These patient-reported data bases could be linked with those containing primary data from computerized medical record or other administrative data bases to support QI efforts. To realize these opportunities we must solve the problems of inconsistent data standards, lack of a unique patient identifier, and lack of acceptable safeguards for patient privacy and data security.

To add to the challenge, data quality concerns have been noted in most studies using automated administrative data bases. Specifically, coding systems are currently inadequate for distinguishing tentative from confirmed diagnoses (Steinwachs and others, 1989), coding practices may differ across institutions, data definitions may vary by institution or payer, and data completeness and accuracy are suspect (Blumberg, 1987, 1988; Campion and others, 1992; Steinberg, Whittle, and Anderson, 1990). All of these problems introduce biases in interpreting the results of such studies.

Progress in meeting data needs. Progress is being made in many of these areas. The tenth revision of the International Classification of Diseases (ICD-10) is expected to address the problem of tentative vs. confirmed diagnoses; payers are increasingly requiring standard data definitions and coding practices; and reimbursement mechanisms that are dependent upon complete and accurate data to assign the proper payment are creating incentives for institutions and clinicians to improve their coding practices.

Some researchers have suggested coding improvements that would build upon current diagnosis and procedure coding schemes at marginal cost to greatly increase the information content of these codes, thereby aiding QI efforts (Janssen, Viste, and Gluck, 1990; Mendenhall, 1987, 1991; Naessens, Brennan, Boberg, and others, 1991). Others have created clear and specific definitions for selected quality and utilization "screening" measures, which may facilitate benchmarking of performance to "best in class" institutions or health plans (Rutstein, Berenberg, Chalmers, and others, 1976; Rutstein, Mullan, Frazier, and others, 1983; Weiner, Powe, Steinwachs, and others, 1990), although some have found these measures to be overly sensitive and insufficiently specific (Sanazaro and Mills, 1991).

Those with access to linked automated data bases within institutions have developed innovative methods for using "downstream" data to identify "upstream" quality problems (Louis and others, 1988; Mennemeyer and Winkelman, 1991), while Canadian researchers have developed methodologies for linking inpatient and outpatient claims to

track quality problems across care settings (Roos and others, 1985; Roos and others, 1987). These methodologies will be useful in the future, should linkage become possible in the United States.

Code "mapping" strategies between ICD-9-CM (International Classification of Diseases, Ninth Revision, clinically modified) and CPT-4 (Current Procedural Terminology, Fourth Edition) procedure codes, where possible, would be highly useful for linking inpatient and outpatient claims data. Agreement between the physician claim and the inpatient or surgical day care claim from the hospital could help validate coding accuracy for procedures performed in institutions.

Information Technologies with QA and QI Applications

Information technology may be defined as software, hardware, and information science theory applied to data bases and information systems to expand their ability to meet users' needs.

Information technology in general use today improves our ability to assess what is occurring in health care delivery but does not substantially improve our understanding of why certain health care processes and outcomes occur. There is a broad range of emerging technologies in prototype or limited production that can be incorporated into QA and QI systems. These innovations, which are being created by medical informatics professionals and adapted from other industries, will help answer both the "what" and the "why" of health care. At the stage of conceptual discussion are additional products of information science and theory, potential technologies whose role in QA and QI is yet to be clearly defined.

Information technologies currently incorporated into QA and QI systems. The most significant impact of current information science, technology, and statistical analysis is their effect on our ability to exploit coded data contained in the electronic data bases discussed above. Four specific aspects of this are codification of data, case mix systems, automated medical records, and expert systems. Codification of data has impact on both administrative and clinical systems and is augmented by use of controlled vocabulary and structured text strings. Case-mix systems allow adjustment for severity of illness and grouping according to resource utilization. Automated medical records have been implemented at a limited number of sites, but they have become fundamental to the operation of health care delivery at those sites. Expert systems applications fall in two categories: monitors that offer retrospective reminders and consultants who offer off-line decision support.

Codification of data. Codification of clinical data facilitates comparison of data when collected by multiple providers or over time. When data systems are automated, codification is necessary to take advantage of the rapid processing speed and integration capabilities that computers provide. Several authors have commented on the advantages of coding in health care, particularly in light of the lack of a standardized nomenclature (Bishop and Dombrowski, 1990; McDonald, 1991; Shortliffe, Perreault, Widerhold, and Fagan, 1990).

In the United States, the most widely used medical coding schemes include the following:

- ICD-9-CM supported by the World Health Organization for inpatient discharge diagnoses.
- CPT-4 supported by the American Medical Association for physician services procedures.
- DSM-III (Diagnostic and Statistics Manual, Third Edition) supported by the American Psychiatric Association for classification of mental disorders incorporating measures of stressors and function.
- HCPCS (HCFA Common Procedure Coding System) for procedures for Medicare claims processing.
- SNOMED (Systematized Nomenclature for Medicine) supported by the American College of Pathologists for pathologic diagnoses and workload codes.
- AHFS (American Hospital Formulary Service) for categorization of medications and prescription items.
- NDC (National Drug Code) supported by the Food and Drug Administration for manufacturer and preparation-specific medication identification.
- ICCS (International Classification of Clinical Services) supported by Healthcare Knowledge Resources for health technology services.

These coding schemes are fundamental to the work of QA professionals. However, there is little in the literature that discusses the specific effects of coding systems on QA. One exception has been the use of ICCS billing data to monitor and improve hospital drug use (Mendenhall, 1987, 1991).

Each of the systems listed above uses numeric or alpha-numeric strings as arbitrary symbols to represent the words that identify an object, process, or concept. This is not the only method of codification of medical information, however, as controlled vocabulary and structured text also serve this purpose.

In a controlled vocabulary (CV), strings of characters that appear to be regular words or abbreviations are used to represent what the words themselves, or other words, represent. Similar to alpha-numeric codes, these coding systems do not permit deviation in content (spelling) or syntax when a specific meaning is desired.

In some situations, the CV serves as a standardized dictionary of usable terms, each uniquely linked to one machine usable code (Clark and Shea, 1990; Masarie, Miller, Bouhaddou, and others, 1991). For example, "thoracentesis" is uniquely linked to the ICD-9-CM code 34.91. Automated systems may accept and report the procedure thoracentesis using either CV or code, although it is unlikely the CV itself would be stored and processed.

In other situations, the CV terms themselves are stored and processed in the automated information system. Frequently used CVs are units of measure, such as "mg" and "cc," as well as positional modifiers such as "left" and "sit."

Structured text is a technique by which meaning is assigned to and extracted from letters and numbers according to their position in a character string. If each segment is always of fixed length, it can be stored and processed according to its character position in the string, like the columns in old-fashioned punched cards. If the length of individual segments can vary, delimiters are necessary for the information system to distinguish the segments.

Case-mix systems. Case-mix systems are designed to categorize patients according to significant characteristics of their medical condition or care received. Using advanced analytic techniques in their creation, and manipulation of enormous administrative and clinical data bases in their design and validation, case-mix systems are a second area in which information technology has an impact on QA. Case-mix systems generally fall into two varieties: those that classify according to resource consumption and those that classify according to severity of illness.

The Medicare prospective payment system is anchored on the diagnosis-related group (DRG) case-mix system. DRGs classify patients of similar clinical type according to a small number of patient attributes and treatment processes found in the UHDDS. Inpatient resource consumption is predicted by DRG, which then serves as a means to define hospital case-mix for internal analysis and comparison between facilities. DRGs thus serve as a common denominator for inpatient QA analyses. Case-mix systems for analysis of ambulatory resource consumption are under active development both within the United States and abroad (Greenlick, 1991; Weiner, 1991; Wood, 1991).

Measurement of inpatient quality of care is improved when patient severity of illness is considered more fully than possible with DRGs. It then becomes more feasible to answer the question: "Who is caring for the sickest patients?" Severity systems allow deeper analysis of the effectiveness, appropriateness, and efficiency of care rendered by considering the effects of comorbidity and complications, as well as permitting, in some systems, review of patient status concurrently and repeatedly during their admission.

A number of commercial products provide tools for severity assessment. Some are fully automatable because they use only electronically available UHDDS elements to determine severity. Others incorporate detailed clinical findings into their severity analysis, requiring manual chart review. Several system vendors also provide national comparative data bases for license holders. Commercial severity of illness measurement systems have been cataloged or compared in the literature (Aronow, 1988; Fifer, 1987; Horn and Buckle, 1989). Noncommercial case-mix systems and their value in QA also have been described (Janssen and others, 1990; Shabot and others, 1987).

As noted by Fifer (1987), the analytic powers of computers have permitted the emergence of case-mix systems and allowed QA to enter "the era of norms." However, continued improvement is needed in the design and use of case-mix systems to account for additional attributes of patient diversity (Green and others, 1991) and increase the

range of electronic clinical data to be integrated into case-mix systems (Shabot, Bjerke, LoBue, and others, 1991).

Automated medical records. The third area in which information technology has affected QA and QI is the automated medical record (AMR) (Dick and Steen, 1991; General Accounting Office, 1991; Shortliffe and others, 1990). Currently, AMRs have been implemented in a limited number of clinical settings. With the exception of those few centers where AMRs have been embraced enthusiastically for a number of years, the AMR should be viewed as an emerging technology. However, because at these institutions the AMR is not an academic prototype, but is relied upon to meet everyday operational needs, they are listed below. General descriptions and bibliographies of these systems are available in recent publications (Agency for Health Care Policy and Research, in press; Dick and Steen, 1991; Shortliffe and others, 1990; Stead, 1989).

- AMRS (Automated Medical Record System) adapted from COSTAR IV and implemented at the Harvard Community Health Plan.
- Beth Israel and Brigham and Women's Hospitals' system.
- COSTAR (Computer-Stored Ambulatory Record) developed at Massachusetts General Hospital and implemented at several hundred sites worldwide, currently in its fifth release.
- DHCP (Decentralized Hospital Computer Program) developed and implemented at nearly 200 sites by the Department of Veterans Affairs.
- HELP (Health Evaluation Through Logical Processing) developed and implemented at Latter Day Saints Hospital.
- RMRS (Regenstrief Medical Record System) developed and implemented at Indiana University Medical Center.
- STOR (Summary Time Oriented Record) developed and implemented at the University of California, San Francisco.
- THERESA developed privately for and implemented at Grady Memorial Hospital.
- TMR (The Medical Record) developed and implemented at Duke University Medical Center.

Compared with paper medical records, several characteristics of AMRs allow them to enhance QA and QI: greater accessibility, more rapid data retrieval, more complete and consistent organization, greater readability, better integration of results reports, and the potential to be more complete and accurate.

The most important benefits, however, are the ad hoc query and monitoring functions AMRs allow, functions that have no corollary in the paper record. As a query tool in QA, the AMR allows the clinical records of large patient populations to be searched according to specified criteria to produce reports at various degrees of summarization. Queries often provide the means for defining study groups for QA projects. Special high-level query languages have been developed for AMRs, including Clinquery at the Beth Israel Hospital, the Medical Query Language (MQL) for COSTAR, STRATO for HELP, and CARE and FAST for the RMRS (Adams, 1986; McDonald, Tierney, Martin, and others, 1991; Pryor, 1988; Safran, Porter, Rury, and others, 1990). Several recent reports describe these activities (Hoffman, Christenson, Brimley, and others, 1990; Payne, Goodson, Morgan, and others, 1989). AMR monitoring functions are discussed in the next section.

Expert systems. Expert systems are a fourth area in which information technology is now incorporated into QA and QI. As defined by Shortliffe and colleagues (1990, p. 653), expert systems symbolically encode concepts derived from experts in a field and use that knowledge "to provide the kind of problem analysis and advice that the expert might provide." Thus, the expert system approach is conceptually very general and is applicable at many levels of complexity.

Two types of expert systems may be distinguished: monitors providing retrospective reminders and consultants offering off-line decision support. There may be overlap of these functions in specific applications, and the current range of application of expert systems will expand with the emerging technologies discussed later in this paper.

Monitors provide automatic surveillance of the clinical data of active patients to look for individuals who have specified data occurrences or patterns of data occurrences. These have been found particularly useful in the delivery of preventive health maintenance. Positive findings (defined by provider-authored rules) generate alerts, reminders, or other

kinds of feedback to providers. Expert monitors are not restricted to AMRs, but their most significant applications are intimately linked to AMRs. Many studies of expert system surveillance contributing to QA have been reported, particularly for three pioneer AMRs: COSTAR, HELP, and RMRS (Barnett, Winickoff, Dorsey, and others, 1978; Barnett and others, 1983; Berwick and Coltin, 1986; Bradshaw, Gardner, and Pryor, 1989; Evans, Gardner, Bush, and others, 1985; Evans, and others, 1986; Evans, Burke, Pestotnik, and others, 1990; Frame, 1990; Harris and others, 1990; McDonald, 1976; McDonald and others, 1984; Norman and Hardin, 1990; Ornstein, Garr, Jenkins, and others, 1991; Pestotnik, Evans, Burke, and others, 1990; Tate and others, 1990; Winickoff and others, 1984).

Consultant expert systems offer the clinical competence of their expert-author panels on an as-needed basis to health care providers. Although there are many such systems in use, few have been reported for their contribution to QA and QI activities (de Dombal, 1989; Evans and others, 1990). Currently, providers use the systems for assistance in caring for individual patients rather than the process and population-based needs represented in QA and QI (Carlson, 1989).

Essential to the operation of any type of expert system is the knowledge base (KB) wherein the system's expertise resides. Included here are the logic rules, weights, facts, and models through which expertise is computerized. KBs are discussed in several recent publications (Giuse, Giuse, and Miller, 1990; Holbrook, Langton, Haynes, and others, 1991; Lincoln, 1990; Perry, 1990)

Emerging information technologies. Emerging information technologies have tremendous potential to enhance QA and QI efforts in health care, particularly for connectivity and use of encounter data. Connectivity is the integration into comprehensive health care information systems of data, information, and knowledge across systems, sites, and time. Issues include:

- Local and regional networking.
- Centralized vs. distributed systems.
- Proliferation of AMRs.
- Data accessibility and portability.
- Workstations as resource centers and integration tools.
- Matching of patient identifiers.
- Development of standards for use of medical data.

Increased connectivity will substantially improve the ability of QA to identify what is occurring in health care. A number of discussions of connectivity issues and benefits to QA and QI have been published (Ball and Douglas, 1991; Cimino and Sengupta, 1991; Dick and Steen, 1991; Glaser, 1991; Kamel and Zviran, 1991; Lansky, 1989; Roos and Sharp, 1988; Selbmann and Pietsch-Breitfeld, 1990; Shortliffe, 1991; Stead, 1991; Zinn, 1990). Additionally, many implementations of integrated health care information systems have been reported (Albright, Panzer, Tuttle, and others, 1990; Bakker, 1990; Branger and Duisterhout, 1991; Edsall, 1991; Hidalgo, 1990; Lansky, 1989; Leyerle, LoBue, and Shabot, 1990; McDonald and others, 1991; Peng, VanDorsten, Dilzer, and others, 1991; Price, Chandrasekhar, and Tamirisa, 1990; Pryor, 1988; Roos and Sharp, 1988; Safran, Slack, and Bleich, 1989; Scherrer, Baud, Hochstrasser, and Ratib, 1990: Weissman, Mossel, Haimet, and others, 1990).

Use of encounter data involves the collection, storage, and interpretation of data from the private meeting of provider and patient. Issues include:

- Incorporation of encounter or progress notes into the automated medical record.
- Data entry by providers.
- Data entry by patients.
- Processing of text data.
- Structure of the AMR.

Encounter data include data that the provider records as history and physical examination, the logic the provider followed to reach documented assessments and diagnoses, and the rationale for orders for diagnostic and therapeutic actions. These data will provide a substantial boost to QI efforts to determine the "why" of health care. Recent publications have discussed these issues, in particular the problems surrounding automation of provider-collected data and the effect of clinical encounter data on QA and QI (Dambro and Weiss, 1988; Dick and Steen, 1991; General Accounting Office, 1991; Hammond and Stead, 1991; Safran, Rusy, Rind, and Taylor, 1991). Issues involved with complementary data entry—data from the patient's encounter

experience—also have been discussed (Thomas and others, 1989; Williams, Imrey, and Williams, 1991).

Interest in both encounter data and quality of care have contributed to experimentation with a variety of AMR formats and data collection mechanisms (Bishop, 1991; Hammond, Straube, and Stead, 1990; Rodewald, Szilagyi, Wrenn, and Slovis, 1991), as well as the growing interest in AMRs evidenced by the recent Institute of Medicine report on computer-based patient records (CPRs) (Dick and Steen, 1991).

Specific emerging information technologies may impact on connectivity or data use or both. Their potential roles will be described in terms of their place in the following QA and QI process. Technologies that pertain to more than one step in the process are discussed in the step where they first appear.

Data capture codification and storage	→ Information processing	→ Knowledge dissemination

Data capture, codification, and storage. The capture and codification of data for administrative and clinical health care information systems provide inputs for QA and QI processes. Information technologies for these activities may be grouped as input mechanisms, standards conventions, and analytic systems.

Emerging input mechanisms allow more rapid, complete, flexible, and quality-checked data capture than is achievable by a trained intermediary using paper and pen in a hardcopy record or AMR data entry. They include scanning, pointing, speech recognition, handwriting recognition, image digitizing, bedside terminals, and provider workstations.

Scanning, using an optical mark reader, identifies "bubbles" filled in on a form and interprets them according to their location. This allows rapid, error-checked data entry to mainframe or microcomputer information systems (Lindemann, Rock, Locke, and Johnson, 1991). Optical character readers scan printed text and translate the characters into American Standard Code for Information Interchange (ASCII) code for storage, retrieval, and possible analysis. Bar code readers translate printed lines to positively identify people and objects, allowing rapid documentation of specimens, medications, or other materials handled, with annotations of persons and places.

Pointing devices include the mouse, touch screens, and light pens which may be incorporated into the interface of workstations or portable terminals. Pointers allow use of icons and menu displays to speed communication with computer systems (McDonald, 1990).

Automated speech recognition (ASR) is concerned with the comprehension of spoken input and the translation of that input into the electronic medium (Belton and Dick, 1991; Bergeron and Locke, 1990; McDonald, 1990). ASR should not be confused with voice recognition, which is concerned with proper identification of a particular speaker. Commercial ASR systems are being used in emergency medicine and radiology, and noncommercial systems are being developed in other specialties (Cass, 1991; Holbrook, and Ontai, 1991; Landau, Norwich, and Evans, 1989; Smith, Brien, Pettus, and others, 1990). Although obstacles remain, this technology holds promise for providing the first means of direct provider entry into the AMR without significant alteration of work flow.

Handwriting recognition, sometimes referred to as pen and pad technology, is combined with portable terminals and pointing devices. Input is made by hand printing characters on forms visible on the computer screen. This technology is minimally developed, but it holds the highest potential for allowing providers to enter data into the AMR with minimal disruption to their work style (Andreshak, Lumelsky, Chang, and others, 1990; Bergeron and Locke, 1990; McDonald, 1990).

Image digitizing and processing has been developing rapidly due to the highly computerized nature of many medical imaging procedures. Picture archiving and communications systems (PACS) are becoming more common in radiology departments and can be expected to spread to other image-rich specialties, such as ophthalmology and pathology. These systems allow automated storage, retrieval, and manipulation of images, making them available to multiple providers at desktop workstations in distant locations. Image analysis and reporting systems are now being prototyped (Dayhoff, Maloney, Kenny, and Fletcher, 1991; McDonald, 1989b; Ratib and Huang, 1991; Rowberg and Price, 1991; Rusinek and Mourino, 1989).

Bedside terminals—both hand-held portable devices and those dedicated to specific patient beds—are designed to allow data capture at the time and place the data are generated (Ball and Douglas, 1991; Higgins, Jiang, Swindell, and Bernard, 1991; Nowlan, Rector, Kay, and others,

1990). Among other goals, these "point of care systems" are expected to minimize recordkeeping time, reduce errors due to manual transcription, perform calculations, and check data for errors. They generally feature graphic user interfaces, and many commercial models are available.

Provider workstations incorporate many of the technologies discussed above into an intelligent terminal or stand-alone computer with high-resolution graphic interface. The workstation itself may be the means to achieve integration of heterogeneous information systems, especially for information retrieval by practitioners (Annevelink, Young, and Tang, 1991; Hammond, Berger, Carey, and others, 1991; McCallie, Margulies, Kohane, and others, 1990; Silva, Zawilski, O'Brian, and others, 1990). Like bedside terminals, workstations may create an environment conducive to provider data entry (Fan, Machlin, Wang, and Chang, 1990). Electronic mail allows communication with other providers, alerts, reminders, and reports. Bibliographic resources are available, as well as other reference materials.

Standards conventions are in development for coded medical data and for definition of data sets, data exchange practices, and the semantics of knowledge representation. These efforts are mutually dependent and affect information processing and knowledge dissemination for QA and QI, as well as data capture (Agency for Health Care Policy and Research, 1991; McDonald, 1991).

Many standards exist for the codification of medical data, as noted previously. However, these are inconsistent in their level of detail and the completeness with which they cover their specialty. Furthermore, there are incompatibilities between code systems for similar domains, such as procedure codes in ICD-9-CM and CPT-4. Finally, codes are lacking for data obtained in history taking and physical examination.

Some of these problems are being addressed by the organizations discussed in the data exchange portion of this section, as well as the American Society for Testing and Materials (ASTM), which is developing a chemistry test nomenclature. Other deficiencies will be improved with the development of new minimum health care data sets.

Currently, health care data sets exist formally as the UHDDS and informally as the HCFA claim forms: UB-82 for inpatient services and HCFA-1500 for outpatient and physician services. However, the UHDDS consists of a limited demographic patient profile with diagnostic and procedure codes, and completion of many of the claims form fields is optional.

The development of several data sets is noted in the Agency for Health Care Policy and Research (AHCPR) (1991) report on linking research-related data bases:

- The Uniform Ambulatory Care Data Set (UACDS) seeks to standardize data on outpatient care from physicians and other providers.
- The Long-Term Care Facilities Minimum Data Set seeks to describe settings of long-term care.
- The Long-Term Care Client Uniform Data Set seeks to describe clients of long-term care.
- The Nursing Facility Resident Assessment Core Data Set seeks to promote uniform clinical and functional assessment of nursing home residents.

Other data sets in development include:

- The Uniform Clinical Data Set (UCDS) seeks to provide patient risk factor, procedure, and outcomes data for expert system analysis by PROs to improve their capabilities for monitoring health care quality (Harrop, 1991; Health Care Financing Administration, 1991).
- The Wisconsin Ambulatory Review Program (WARP) seeks to develop a matrix of clinical findings, attributes applicable to the findings, and intensity scales for the attributes for analyzing ambulatory care quality (Yanke and Moskowitz, 1992).
- The Nursing Minimum Data Set (NMDS) seeks to define a core set of data for assessing nursing practice across settings (Delaney and Mehmert, 1990; Werley, Devine, Zorn, and others, 1991; Williams, 1991).

The only data exchange or message standard currently in prominent use is the ASCII code which operates at the individual character level. Several organizations are actively designing medical data exchange standards at higher levels to facilitate communication within and between health care facilities (Agency for Health Care Policy and Research, 1991; McDonald, 1991; McDonald and others, 1991; McLinden, D'Ascenzo Carlos, and Oleson, 1990; Shortliffe, 1991). These include:

- ACR/NEMA (American College of Radiology/National Electrical Manufacturers Association) is developing standards for PACS.
- ASTM subcommittees are developing standards for physiologic data, reminder systems logic, and data exchange between computer systems.
- CEN (European Standardization Committee) is developing data exchange standards in Europe.
- HL7 (Health Level Seven) health care providers, vendors and consultants are developing exchange standards for health care computer applications.
- MEDIX (Medical Data Interchange Committee of the Institute of Electrical and Electronic Engineers, IEEE) is developing exchange standards according to American National Standards Institute (ANSI) consensus rules (Harrington, Benson, and Spector, 1990).
- MIB (Medical Information Bus of the IEEE) is developing exchange standards between medical devices and computers (Nolan and Shabot, 1990).

In the United States, many vendors and providers have announced adoption or support of interfaces to the HL7 and/or ASTM standards. These two organizations have worked closely to make their efforts complementary. Communication between medical data exchange standards-setting organizations has been provided by the Healthcare Information Standards Coordinating Committee, and beginning in 1992, ANSI also will help coordinate standards-setting efforts.

Another aspect of message exchange concerns standardization of network systems. The Integrated Systems Digital Network standard attempts to address this need (Agency for Health Care Policy and Research, 1991).

A final level of standards development concerns exchange of medical knowledge. The Arden Syntax for Medical Logic Modules, derived from analysis of the knowledge bases of the HELP and Regenstrief ARMs, has been proposed (Hripcsak, 1991; Hripcsak, Clayton, Pryor, and others, 1990; Prokosch, Kamm, Wieczorek, and Dudeck, 1991). Because development of medical knowledge bases is so costly and time consuming, and the benefits of sharing organized knowledge are so great, the ASTM has created a new subcommittee on Health Knowledge Representation.

Analytic systems as emerging information technologies include natural language processing, expert systems, and transaction processing systems.

Most provider documentation is text—that is, handwritten, typewritten, transcribed dictation, notes entered directly or through an intermediary into an AMR, or electronically stored voice recordings. This has made it very difficult for QA and QI professionals to locate desired findings, conditions, and actions. When text is linked to coded data, identification of relevant records is easier, but the burden of manual text review remains overwhelming.

Natural language processing (NLP), the capacity of automated systems to extract meaning from text data, is fundamental to increasing our ability to measure, assure, and improve health care quality. NLP can be applied to text for indexing, codifying, abstracting, and interpreting medical documentation and information resources. There is active research and prototyping being done using a variety of analytic approaches for these functions, much of it explicitly linked to QA and QI (Gabrieli and Speth, 1990; Hersh and Greenes, 1990):

- Discharge summaries are abstracted for asthma management audit (Lyman, Sager, Tick, and others, 1991).
- Discharge summaries are audited for quality of care problems (Gabrieli, Pollock, Beltrami, and others, 1989).
- Discharge summaries are abstracted to create patient profiles (Borst, Lyman, Nhan, and others, 1991).
- Discharge summaries and operative notes are stored and indexed in a text data base (Ribitzky, Waterman, Zieman, and others, 1990).
- Orthopedic diagnoses and procedures are indexed to facilitate clinical research (Floyd and Kinser, 1990).
- Pathology reports are coded and abstracted to SNOMED controlled vocabulary (Moore and Berman, 1991).
- Emergency department records are audited for key findings based on "trigger diagnoses" (Holbrook and Aghababian, 1990).
- Admission summaries are abstracted to yield physical examination findings to enrich an

existing clinical data base (Lin, Lenert, Middleton, and Shiffman, 1991).

- Literature abstracts are indexed using a thesaurus (Evans, Hersh, Monarch, and others, 1991).

There also are commercial NLP systems available. One class of product provides a user-friendly interface to relational data bases by translating natural language queries into the structured query language of the data base. A second class of product is provided with ASR systems to allow real-time coding and interpreting of speech input. When coupled with an expert system, quality review is possible concurrent with automated data entry (Holbrook and Ontai, 1991).

Expert systems were introduced earlier in this paper and examples provided of their incorporation into established, operational information systems. Research and prototyping of more advanced expert system applications and the knowledge bases supporting them flourish, particularly in departmental information systems and in conjunction with other emerging information technologies (Lincoln, 1990; Lipscombe, 1989):

- Drug treatment of psychiatric patients is monitored for deviations from guidelines or abnormal lab results (Bronzino and others, 1989).
- Selected clinical findings are abstracted from an AMR and reported to a radiologist by an expert consultant system to assist in x-ray interpretation (Haug and Beesley, 1991).
- Diaries of cystic fibrosis patients in a home monitoring program are monitored for data quality and health status (Slagle, Finkelstein, Leung, and others, 1989).
- Ambulatory drug utilization is monitored with reminders and chart audits (DeNeef, Ellsworth, and Schneeweiss, 1991).
- Insurance claims are monitored to identify readmissions due to surgical complications (Roos and others, 1985).
- Computer-assisted QA is developed for a respiratory care program (Elliot, 1991).
- A PRO's identification of quality problems using the UCDS is compared with an expert diagnostic system (Lau and Warner, 1991).
- Blood ordering practices can be modified through the use of a consultation system (Lepage, Gardner, Laub, and others, 1991).
- Treatment of hypertension patients in an AMR setting is monitored and critiqued (Van der Lei and Musen, 1991).
- A consultative expert system for cholesterol management uses a hypertext interface (Kane, 1990).
- A rheumatological expert system uses a knowledge base of highly detailed anatomical knowledge (Horn, 1991).

Transaction processing systems (TPSs) are a general class of information systems that monitor processes in another operational system and trigger specific actions if certain predefined events occur. Thus TPS provide real-time feedback based on expert system rules. The term TPS is not frequently used in health care informatics, but it is applicable to systems as simple as error-checking by an intelligent bedside terminal during interactive data entry and as complex as the evaluation by expert systems of the pattern of codes produced by NLP of speech data entry. In each case, a transaction of data entry is monitored and potentially interrupted before completion because of the content of the data.

Particularly pertinent to provider data entry is the interface approach of context-sensitive prompts and defaults. In this application, a TPS monitors user input and selects the most appropriate next message for display based on that input. For example, a practitioner entering a patient's complaint of sore throat might be prompted to document the presence of coughing, and if present, its productiveness. Similarly, when prescribing medications, the provider may be offered the most commonly used dose and form for the patient's age, subject to replacement with other values. The concept of transaction processing is critical to improved data quality and the incorporation of clinical guidelines into real-time documentation of patient care.

Emerging data storage technologies of importance to quality efforts include magnetic disk drives with increasing capacity and mean time between failures rated at over 5 years, optical disks, and portable memory. Like magnetic storage, the optical disks—where lasers are used to permanently write data onto minute segments of disk—will help meet anticipated needs for huge storage capacity as AMRs proliferate and integrate increasing numbers

of data sources, in particular ASR-captured dictation and PACS-captured images.

Optical disc technology provides access to reference sources as well as mass data storage (Brahmi, 1989). Several vendors produce compact disc read-only memory (CD-ROM) discs of bibliographic, pharmacologic, and textbook data bases. Prototypes have been developed that incorporate these data sources into provider workstations. Health care organizations with mobile patient populations and independent care sites also are producing their own CD-ROMs to provide current, core medical records at all delivery sites (Demetriades and Gomez, 1991).

Portable memory, allowing patients to carry medical data and make it available to providers or vendors unacquainted with them, comes in the form of optical (laser) and integrated circuit (smart) cards. Optical cards have a memory capacity of up to 4 megabytes of data and may hold text and image data (Bouldin and Callen, 1990; Brown, 1989; Gomez, Demetriades, Babcock, and Peterson, 1991; Shiina, Nishibori, Matsuzaki, and others, 1991). They are write-once read-many (WORM) cards, so they are updated by adding current data without deleting prior data. Integrated circuit cards contain an electronically-erasable, programmable, read-only-memory (EEPROM) microchip with a capacity of 16 kilobytes of data (Benson, 1990; Hopkins, 1990; Ognibene, 1991; Regan, 1991; Smart cards in Medicine, 1990). An essential medical record can be written, erased, and edited.

Finally, data storage technology now supports digitization of sound. This may be used on a temporary basis to make dictation available as part of an AMR until it is transcribed into the record. In the longer term, voice and sounds from both providers and patients—including heart and breath sounds and examples of speech pathologies—may be digitized to become permanent parts of the medical record (McDonald, 1989a).

Information processing. The core information processing work of QA and QI will benefit from information processing technologies of three types: systems integration, text processing, and expert systems. Integration advances include data exchange standards, patient identification (ID) matching, developments in systems architecture, and high-speed network data transmission. Individual types of exchange standards have been discussed above and will contribute to information processing for QA and QI.

Of particular importance is the work by the National Library of Medicine (NLM) to develop the Unified Medical Language System (UMLS). UMLS is designed to facilitate communications between both different electronic systems and different institutions by creating a system for mapping and interpretation between diverse coding systems and controlled vocabularies (Cimino and Sideli, 1991; Humphreys, Lindberg, and Hole, 1991; Lindberg and Humphreys, 1990; Masarie and others, 1991; McDonald, 1991; Sherertz, Olson, Tuttle, and Erlbaum, 1990). COSTAR, CPT-4, DSM-III, DXplain, HELP, ICD-9, and SNOMED codes have been included, as well as the Medical Subject Headings (MeSH) used by the NLM. It is expected that UMLS will provide a cornerstone for NLP of medical text, and it has been incorporated into the ASTM data exchange standards.

Closely related to UMLS is the Integrated Academic Information Management System, also supported by the NLM. This project involves a number of sites experimenting with communications and information processing technologies for the development of integrated health care information systems (Cimino and Sengupta, 1991; Lincoln, 1990; Shortliffe and others, 1990). Data exchange and the interpretation of data between systems are the goals.

Patient identifier matching is another cornerstone for integration of information systems for QA and QI. According to AHCPR (1991, p. 3–2), "The greatest technical impediment to linking personal data files is the lack of a standard personal identifier." Institution and system identifiers are not coordinated and may change over time. In many nonmedical information systems, the social security number has become a de facto standard individual identifier. The social security number is being promoted for adoption in health care by the National Committee on Vital and Health Statistics of the U.S. Department of Health and Human Services (Agency for Health Care Policy and Research, 1991). Meanwhile, institutionally based alternatives for patient data matching are being studied (Fair, Lalonde, and Newcombe, 1991; Hammond, Stead, and Straub, 1990; Sideli and Friedman, 1991).

Classical systems' architecture is highly centralized and based on mainframe computers. Many institutions are experimenting with and implementing other configurations, both distributed and based on personal computers or workstations, and both

interfaced and integrated, to facilitate the processing and integration of medical information (Curtice and Glaser, 1989; Dayhoff, Maloney, and Kuzmak, 1990; Ellis, 1990; Hammond and others, 1990; Margulies, McCallie, Elkowitz, and others, 1990; Price and others, 1990; Stead, Borden, Boyarsky, and others, 1991; Tang, Annevelink, Fafchamps, and others, 1991; Young, Tang, and Annevelink, 1991).

A final, closely related technologic advance is the development and diffusion of high-speed data communications through local and regional networks (Dick and Steen, 1991). Fiber-optics and the Integrated Systems Digital Network permit rapid, low-cost digital networks for voice, data and image retrieval and transmission between disparate, decentralized, and independent data sources and may permit the development of a virtual AMR.

Knowledge dissemination. Knowledge dissemination, a key product of QA and QI, also will benefit from information systems integration. This is particularly true in QI, where successive incremental lessons and interventions can be implemented with the aid of the integrated system, and a new cycle of monitoring can begin. In addition, advanced decision support and executive information systems will promote knowledge dissemination. Their success, like that of the AMR, will be linked closely to maturation of the graphic workstation with intelligent/intuitive data display and interactive feedback concerning treatment plans via TPS (Hammond and Stead, 1991; Higgins and others, 1991; Kawahara and Jordan, 1989).

Undeveloped information technologies. Shortliffe and colleagues (1990, p. 20) define medical informatics (MI) as "the rapidly growing scientific field that deals with the storage, retrieval, and optimal use of biomedical information, data, and knowledge for problem solving and decision-making." Equating MI with the term medical information science, they note that it includes the application of computers to medicine—broadened to include medical statistics, recordkeeping, and the study of the nature of MI—with a de-emphasis of the computer itself while focusing on the nature of the field to which the computations are applied (Shortliffe and others, 1990, p. 19). Other authors also have discussed this new discipline, including those who have adopted it as their profession (Aronow, Payne, and Pincetl, 1991; Ball and Douglas, 1990; Braude, 1990; Lincoln, 1990).

From the field of MI come underdeveloped and as yet undeveloped systems and technologies that may have a significant effect on QA and QI. These technologies include advances in knowledge representation and navigation, theory concerning information uncertainty and incompleteness, computer modeling, artificial neural networks, and data base management systems.

Knowledge representation in KBs is important for information exchange between automated systems and for retrieval and comprehension of that information (Hersh and Greenes, 1990; Lincoln, 1990; Perry, 1990). Building on the NLP research discussed earlier, areas of research include:

- Frame-based representation (Evans, Monarch, Rothwell, and others, 1991; Masarie and others, 1991).
- Belief networks (Cousins, Frisse, Chen, and Mead, 1991; Deleu, Beuscart, Becquart, and others, 1989).
- Semantic networks (McCray and Hole, 1990; Rector, Nowlan, and Kay, 1990; Vries, Marshalek, D'Abarno, and others, 1992).
- Spatial knowledge representation (Srihari and Zhigang, 1989).
- Symbolic representation (Wagner, 1991).
- Use of the Arden syntax (Prokosch and others, 1991).
- Representation through standardization of semantics (Galeazzi, Gangemi, Rossi Mori, and others, 1991).
- Diagnosis of multiple disorders through creation of problem decompositions (Wu, 1990).

Closely related to issues of the representation of knowledge is the problem of access to and navigation through relevant knowledge (Estey, Oliver, Chueh, and others, 1990). A main focus of research here has been the use of hypermedia, such as hypertext interfaces to expert consultant systems for cholesterol management (Kane, 1990), diagnosis of the acute abdomen (Harvey, Moodie, Reda, and others, 1991), and the entry and QA of interpretive pathology reports (Berman, 1991), as well as the approach of "knowledge management" (Greenes, Tarabar, Krauss, and others, 1989).

Management of uncertainty has been problematic in the development of clinical expert systems. Several approaches have been studied at Stanford University (Shortliffe, 1991). Further:

- Uncertainty as a form of entropy in information systems has been modeled as a measure of physician attention to patient data (Gage and Frey, 1991).
- Automated extraction of relative degrees of importance has been used to cope with uncertainty in expert systems (Hudson and Cohen, 1990).
- Augmented decision tables have been used to manage probabilistic data in algorithms (Shiffman and Greenes, 1991).
- Probability tree software supporting random parameters has been developed (Dittus, Roberts, and Wilson, 1989).

Computer-based modeling allows for the simulation of a system, process, or organization to test its performance under stressors. Research in this area includes:

- Simulation of the effect of poor quality data on a QA screening data base (Pine, Rogers, Morgan, and others, 1990).
- Modeling for intervention assessment of risk factor modification (Bloom, 1990; Zhuo, Gatewood, and Ackerman, 1990).
- Use of chaotic models to explain nonlinear dynamic systems (Cohen, Hudson, Moazamipour, and Anderson, 1990).

Artificial neural networks (ANN) are structures of parallel information processors that can be trained to perform complex analyses. Experimentation is underway to develop ANNs to interpret medical images (Piraino, Amartur, Richmond, and others, 1991); detect malignancy during analysis of urine specimens (Cohen, Hudson, Banda, and Blois, 1991); diagnose thyroid conditions (Bolinger, Hopfensperger, and Preston, 1991); facilitate speech recognition (Kurogi, 1991); aid in nursing diagnosis (Harvey, 1990); and perform clinical diagnosis of dementia (Mulsant, 1990).

Data base management systems (DBMSs) are critical to efforts to store, integrate, and retrieve data, information, and knowledge. Relational DBMS have become prominent in health care settings in the last decade due, in part, to their promises of portability and flexibility in response to changing needs of clinical managers (Barsalou, Chavez, and Wiederhold, 1990; Friedman, Hripcsak, Johnson, and others, 1990; Stahlhut, McCallie, Waterman, and Margulies, 1990). Their impact on QA and QI is not clear, although vendors are marketing NLP interfaces to relational DBMSs to facilitate ad hoc query. Object-oriented DBMSs are just beginning to be explored in health care. As the types of data used in the AMR and QA and QI efforts continue to expand to include usable text, complex images, sound, and full-motion video, health care data bases may need to be distributed intentionally to optimize DBMS characteristics with specific data types (Dick and Steen, 1991).

Newer technologies, yet to be tested in health care information systems, include holography, automated vision systems (Harvey, DiCaprio, Heinemann, and others, 1990), brain wave data entry (McDonald, 1990), and interactive video disc presentations for patients, with computer recording and analysis of their health outcome preferences (Patrick, 1991).

Pragmatic and Policy Issues

The most difficult issue facing the field of information science is that of protecting the privacy and confidentiality of data. Issues related to the development and adoption of uniform standards for information exchange have technologic solutions near at hand, and leadership in adopting a specific set of standards for MI systems at the Federal, State, and professional society levels can greatly accelerate the widespread implementation of uniform standards. The adoption of a common patient identifier is methodologically and technically quite simple but legally and ethically complex. Such an action will make the linkage of multiple data bases at the patient level a straightforward technologic procedure that can be executed at any site having access to the necessary data bases. Likewise, emerging information technologies offer new capabilities to access and manipulate that data. Our current inability to safeguard the security, privacy, and confidentiality of such patient data stands out as a formidable barrier to widespread adoption of technologic advances in information processing to support QA and QI.

Concern over widespread computer access to private information is growing among the general public and among professionals in the information technology field (Brannigan and Beier, 1990; Weingarten, 1992). The development of technologic solutions for ensuring data security and confidentiality is becoming a high priority, not only in health care, but in many other industries that collect and process sensitive information (Cobb, 1992). Recent advances in information technology offer some promising improvements in data and systems security, such as call-back modems for remote dial-up access and relational DBMSs that allow controlled access at the row, column, or cell level, depending on the user ID and device. However, additional work in this area is needed if the widespread use of shared data bases for QA and QI is to become a reality (Agency for Health Care Policy and Research, 1991; Dick and Steen, 1991; General Accounting Office, 1991; Lohr, Yordy, and Thier, 1988; Regan, 1991; Walsh and Cortez, 1991).

Another issue is related to the data itself. Two sets of activities are needed: first, we must accelerate the definition of uniform minimum data sets, and their development and reporting by institutions must be mandated by policy, as with UHDDS, or the data bases necessary to support QA/QI efforts will not be available for linkage. Second, we must improve data quality through the widespread adoption of uniform coding practice standards and the auditing of compliance with these standards. Roper and Hackbarth (1988) stated that one of HCFA's most important goals should be to increase the volume and quality of information available to the public. However, many authors have cited data quality problems in currently available administrative data bases and have called for improvements in both the kinds of data available (Blumberg, 1987; Chassin and others, 1989; Kahn, Brook, Draper, and others, 1988) and the accuracy and consistency of coding practices (Blumberg, 1988; Lohr and others, 1988). Data quality is a fundamental concern. It will be a hollow victory if we succeed in addressing the legal, ethical, and technologic barriers to data base linkage and access only to find that the resulting diamond is really coal.

Future Research Directions

QA and QI increasingly require integration of data and information across computing environments, delivery sites, and time. Research on the legal, ethical and technologic issues involved in data linkage is crucial to progress in this area. We also need to define the degree to which patients can and should be responsible for their own medical records (to allow greater use of portable records). Examples of pertinent research areas and questions include:

- Who needs access to automated systems and for what purposes? What level of privacy protection is acceptable to the general public?
- How can information technology be used to provide acceptable levels of patient privacy and confidentiality while permitting access to clinical data for legitimate users?
- What are the options for common patient identifiers and how can information technology facilitate their incorporation into diverse and at times parochial environments?
- How can information technology be used to create longitudinal, multisite, multisystem data bases for care delivery and research?
- At what site should data integration occur? Should it be based at the user interface, the physical system network, in centralized data bases, or all three?
- How can information technology be used to facilitate the integration of inpatient and outpatient data?

A second set of questions involves our ability to measure and improve data quality:

- What is the level of sensitivity and specificity for important data elements in current automated data bases?
- What degree of variation in coding practices exists across care settings and caregivers, and what biases does this variation introduce?
- What mechanisms can be developed to enhance and ensure coding consistency across institutions and practice sites?
- Is direct data entry by practitioners essential for collecting data of the quality needed to support clinical QI?

Additionally, research is needed on those areas in which emerging technologies are already being applied: connectivity and adoption and use of CPRs. Of particular importance to connectivity is the

refinement and promulgation of uniform data sets to permit collection and comparison of data across sites, systems, and time. Essential to this effort is the refinement of technical standards and their adoption by the health care industry. This work should be expanded to standardization of structures for text data and knowledge representation. Examples of pertinent research issues include:

- What is the range of actual and potential uses of uniform minimum data sets for different types of care?
- How can we encourage the development and reporting of uniform minimum data sets?
- What current and additional data elements are of greatest benefit to QA/QI and outcomes research?
- How can research data sets be refined so they are moderate in size, contain easily accessible, well defined data elements, and have clear and focused intended uses?
- What definitions should be applied for coding such entities as "reason for visit," "chief complaint," and "presenting problem"?
- How can we incorporate UMLS and/or other data dictionaries to help standardize coding?
- How can the incorporation of UMLS or other data dictionaries support system connectivity and quality of care?
- Should we establish a uniform procedure coding system or develop code mapping for linking inpatient and outpatient procedure data?
- How can information technology be used to standardize definitions of outcomes and episodes of care appropriate to different settings?
- How can information technology be used to establish data source alternatives to claims data for QA and QI, such as dictated summaries and regulatory abstracts?
- What is the cost/benefit ratio of retrieving and analyzing free text as opposed to controlled vocabulary or coded data?
- How can portable medical records serve an integrative function?

Research into factors that influence the adoption and use of CPRs is vital to the development and promulgation of an important data source to support QA and QI and improve the delivery of health care. A major factor for encouraging greater use and accuracy of encounter data is its method of capture in the
CPR. Data capture through direct entry by providers at the time of the visit will speed the improvement of clinical computing systems as well as their integration with operational and financial systems. Practitioner work flow and information needs must be better understood, and efficient, acceptable interfaces must be developed to encourage direct data entry. As automated records gain acceptance, progress will be needed in their incorporation of expert systems, alone and in conjunction with transaction processing systems, to improve the delivery and monitoring of health care and the dissemination of knowledge gleaned through QA and QI efforts. Important areas for further research include:

- What are the data and information needs of practitioners that are best met through CPRs?
- What apprehensions do practitioners have concerning use of automated systems, and how can they be overcome?
- Are there clinical work styles that differentiate medical specialties and affect systems implementation?
- How can information technology be used to provide practice aids?
- Can demonstration projects convince practitioners of the positive effects on quality and cost of automated systems?
- Are there failed system implementations that can provide lessons for practitioner engagement?
- What is the potential for notebook and pen-based computing and for automated speech recognition in facilitating direct data entry by clinicians?
- What is the potential for natural language processing to facilitate practitioner data entry and conversion of practitioner text notes into coded and searchable data?
- What is the cost/benefit ratio of practitioners providing text as opposed to controlled vocabulary or coded data?

- How can clinical practice guidelines be incorporated into automated systems in an acceptable fashion?
- How can transaction processing of health care interactions be implemented to provide real-time decision support?
- How can expert systems support clinical practice and QA/QI?
- What is the most cost-effective design/configuration for a clinician workstation?

Another important area for research concerns the potential for information technology to enhance our ability to collect data directly from patients, make it available to clinicians at the time when it is most useful for assisting their decisionmaking, and use it to support QA/QI. Patients are the principal source of most clinical data but have had the least involvement with automated medical information systems. Their role as both suppliers and consumers of health care information is expanding. Important research questions in this area include:

- How can information technology be used to provide for patient self education?
- How can information technology be used to support more rapid triage of illness or injury, particularly from sites outside of the care delivery setting?
- How can information technology be used to automate medical history collection and the prompting of automated reminders addressed to the patient, with or without provider involvement?
- How can patient needs, preferences, and satisfaction be captured, measured, and reported using information technology?
- How can information technology be used to collect data on health care outcomes directly from patients? What accuracy and efficiency gains are achievable using these technologies?

Finally, we need to explore the extent to which information technologies can be used to improve our capabilities and efficiency in measuring and improving the quality of health care, such as:

- How can information technology improve quality measurement and reporting?
- What aspects of care delivery are currently measurable using automated data bases, and how can information technology be used to increase and diversify the measurable attributes?
- How can information technology be used to more accurately and efficiently measure desired attributes of care delivery?
- How can information technology improve the creation and application of case mix systems and severity of illness and health risk indexes to identify variables affecting quality of care?

Improved knowledge in these areas will greatly facilitate QA and QI efforts to understand and improve the quality of health care.

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Using Information in Quality Improvement and Quality Assurance

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Editors' note: *The Agency for Health Care Policy and Research commissioned this paper to provide a forum for two leaders in their respective sectors of the health care community to examine, from very different perspectives, the uses of information in quality improvement and quality assurance. In the first sections of the paper, Dr. Robert Panzer examines issues of definitions, indicators, measurement, and applications from the perspectives of physicians and institutions providing heath care. In the later sections, Carol Cronin examines issues surrounding quality assessment and improvement from the perspective of purchasers of health care, including employers, groups of employers, or groups of employees who affiliate to purchase or influence the delivery of health care. Both authors raise a number of issues and concerns about the validity of quality of care information and how this information can be used productively. There are, however, marked differences in how these two authors, and the communities they represent, view issues such as public disclosure of quality-related findings and the potential costs and benefits of applying less-than-perfect measures to assessment of provider performance. Research on the topics they identify could shed considerable light on how both providers and purchasers might serve as agents for quality assurance and quality improvement.*

Introduction

In this paper we use the term "quality information" to describe the general concept of information used in quality improvement (QI) and quality assurance (QA). Our discussion is divided into three sections: (1) use of quality information by institutions and clinicians who are the major suppliers of health care, (2) use of quality information by patients and purchasers who are the major customers of health care, and (3) conclusions and identified research needs.

The fields of QI and QA are dynamic, as is the American health care system. In this paper, we present perspectives based on both knowledge about the present and possibilities for the future. One might summarize the present as a situation where QA approaches are more prevalent than QI approaches, and where the application of both QA and QI information is often incomplete or scientifically questionable. Given the very sparse current knowledge about QI in health care, we project available information into a future where QI outweighs or incorporates QA. We also consider information use for QI in the current health care system.

Definitions of continuous quality improvement (CQI) and total quality management (TQM) vary. For the purposes of this paper, we use QI, CQI, and TQM interchangeably to refer to approaches that involve organizational transformation, strategic quality planning, cross-functional management, and process improvement through methods such as QI teams, systems thinking, use of quality tools, and customer "mindedness." We generally use QA to describe various processes of internal and external oversight of health care quality. In any case, use of information crosses all these boundaries.

The focus of CQI mirrors the intent of traditional QA: outcomes (for example, products), process (for example, systems), and structure (for example, design) are all key parts of the CQI approaches. However, in industrial QI translated to health care, proven relationships between components of CQI and quality of care are lacking. The current approach to QI in formal CQI tends to focus on definition of the key process or outcome measures as part of the activities of special teams working to improve a process or resolve a problem. Information on customer satisfaction is of special interest, and relevant measurement systems have become increasingly sophisticated in recent years (Nelson, Hays, Larson, and Batalden, 1989; Nelson,

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Landgraf, Hays, and others, 1990; Nelson, Larson, Davies, and others, 1991; Nelson, Rubin, Hays, and Meterko, 1990; Nelson, Ware, and Batalden, 1990). Cross-departmental quality activities analogous to QA systems are also a well defined part of full CQI models (Malcolm Baldrige National Quality Award, 1991).

Use of QI and QA Information by Health Care Providers

The use of quality information by providers and customers of health care often overlaps. However, the following sections emphasize uses that are predominantly provider oriented, whether the information was generated by the provider or by an external agency.

Often, the application of QA by providers of care is criticized for excessive focus on support processes and structure rather than actual clinical processes. QI efforts, as well, are criticized for focusing predominantly on support and administrative processes unrelated to patient care. There are certain themes, however, that are clearly emphasized more in QI than in QA. For example, a typical QA program might assess patient access to a service by looking primarily at structural aspects such as hours available and staffing patterns. A QI effort in the same area would be more customer-oriented; might rely on patient satisfaction surveys to measure performance (Cleary and McNeil, 1988; Cleary, Keroy, Karapanos, and McMullen, 1989; Nelson and others, 1989; Nelson, Landgraf, Hays, Wasson, and others, 1990; Nelson, Larson, Davies, Gustafson, and others, 1991; Nelson, Rubin, Hays, and Meterko, 1990; Nelson, Ware, and Batalden, 1990); and would look at the system of making appointments as a process to improve, regardless of whether problems were perceived.

Although the QA model does not explicitly foster it, many internal and external QA programs applied to providers are "bad apple" oriented, with a focus on finding problems and someone to blame (Berwick, 1989). Incident reporting systems internally and peer review organization (PRO) activities externally tend to have this emphasis. A QI approach to identified problems would focus more on a search for the process and systems improvements suggested by the individual situation.

Levels of Information Aggregation

Both QI and QA information may be aggregated at different levels for use by providers of care:

- Individual incident—for example, a medication error.
- Patient—for example, an unexpected death.
- Physician—for example, increased adverse outcome rate.
- Procedure—for example, perforations during endoscopy.
- Condition—for example, postmyocardial infarction mortality.
- Unit—for example, intensive care unit severity-adjusted mortality.
- Service—for example, cardiac surgery outcome rates.
- Institutional—for example, composite report of clinical indicators.
- Multi-institutional—for example, comparative adjusted outcomes at community, regional, State, and national levels.

The statistical and clinical significance of apparent deviations varies at these levels of aggregation, as does the target of the analysis.

Models of Quality Information Use

Since much of the QI and QA activity nationally is guided by the Joint Commission on Accreditation of Healthcare Organization (JCAHO) standards, JCAHO directions in information use and recent changes in those directions are important for formulating research questions.

The JCAHO's quality standards have been in evolution for several years. In the mid-1980s, an "agenda for change" began with a movement to develop a core set of clinical indicators for various areas where data could be collected in each hospital, aggregated nationally, and used both for comparative performance evaluation and by hospitals internally to help them identify areas for improvement. More recently, a QI orientation has been added to the JCAHO's standards (starting with education of senior management) without abandoning the clinical indicators efforts (O'Leary, 1991).

The JCAHO *Accreditation Manual for Hospitals* (1992) incorporates a number of revisions with the stated purpose of simplifying and improving the standards related to QA functions in hospitals. The improvements are framed as ones that would "help hospitals overcome common weaknesses in current QA practice." The weaknesses described in the *Manual* involving use of quality information represent areas for future research:

1. A focus on clinical aspects of care alone, rather than the full range of "governance, managerial, support, and clinical processes that affect patient outcomes."
2. Compartmentalization of QA activities according to hospital structure rather than the flow of patient care where processes are "often cross-disciplinary and cross-departmental."
3. A focus on the problem performance of individuals rather than how well processes of care are performed, coordinated, integrated, or improved.
4. Initiating action only for identified problems rather than searching for ways to improve processes.
5. Separating appropriateness and effectiveness from efficiency of care.

Comprehensive QA Information Systems

QA program software. Numerous proprietary and shared software systems are described here and elswhere in this volume. The core of many of these systems is a data base for managing QA activities, for example, incident tracking, infection control, transfusion reaction, and medication error modules. Some of these systems are "shells" where the institution defines measures and data collection mechanisms, and the software stores whatever is provided. Others add to this a set of prototype measures, typically built around various clinical indicators and quality markers.

Outcomes-focused systems. The APACHE system (Civetta, Hudson-Civetta, and Nelson, 1990; Knaus, Draper, Wagner, and Zimmerman, 1986), MedisGroups system (Brewster, Karlin, Hyde, and others, 1985), and the Computerized Severity Index are examples of outcomes oriented systems that focus on severity-adjustment of outcomes to guide institutional decisionmaking.

In each case, comparison of observed with expected outcomes, adjusted for patient mix (demographics, case mix, and severity), leads to flags of areas where performance deviates from the norm (DesHarnais, 1990; Fink, Yano, and Brook, 1989; Flood, 1990). These comparative data provide flags for internal action but generally lack the process data of QI-oriented benchmarking systems.

The literature is mixed with regard to the quality of severity adjustments and particularly the validity of determinations regarding deviant patterns (Aronow, 1988; Iezzoni, 1989, 1990a). For example, questions have been raised about the MedisGroups system regarding the accuracy of its severity adjustments and the validity of its major morbidity measure (Iezzoni, 1987; Ash, Coffman, Iezzoni, and Moskowitz, 1991; Iezzoni and Moskowitz, 1988).

Current internal uses of information. Many reviews of internal uses of quality information suggest that in formal QA programs information is often used more to meet regulatory requirements than to meet internal needs to improve care processes. However, newer models of quality information use are compatible with both QI and QA approaches, including outcomes management (Ellwood, 1988) and clinical indicator systems with cooperative data collection across institutions (e.g., Maryland and Minnesota multihospital clinical indicators projects).

Use of Quality Information by Providers: Key Questions

One of the central questions regarding the use of information by providers of care is "which aspects of the quality review process are most effective in bringing about positive changes in practitioner, organizational, or consumer behavior?" The literature provides little or no experimental data to answer this question. However, extrapolation of information from the many case studies, demonstrations, and opinion papers suggests some answers. There appear to be different themes for effective internal and external quality review.

For internal quality review, a nonpunitive feedback of meaningful clinical information to providers of care is generally most effective, especially when clinicians participate in the design of the measures and when information is aggregated at the condition level. This is compatible with QI, and many of the automated clinical information systems take this approach.

Benchmarking appears to be most effective for external quality review. Such an effort seeks to gather information about the outcomes of care for different providers. In QI, efforts to find these differences are part of a search for the best processes by looking at those with the best outcomes. The focus is the opposite of many current external reviews that concentrate on those with the worst outcomes. It is noteworthy that many current external review systems start with a stated emphasis on finding those with better outcomes, but actual practice deviates.

Examples: Quality Review of CABG Surgery

There are a number of published reports of recent uses of quality information in the area of coronary artery bypass graft (CABG) surgery that illustrate themes of effective quality review.

Northern New England Cardiovascular Disease Study Group. The efforts of the Northern New England Cardiovascular Disease Study Group provide a model for effective quality review (O'Connor, Plume, Olmstead, and others, 1991). The study group is a research consortium with voluntary participation. Some would classify it as an example of multi-institutional internal review, while others would see it as a model of external review. Features of this model consistent with the best QI and QA themes include:

1. A focus on patients with a defined clinical condition, those undergoing CABG surgery.
2. A population base with all 5 cardiac surgery centers and all 18 cardiothoracic surgeons in the region participating.
3. Prospective collection of data from consecutive cases.
4. Definition of data to be collected through a joint effort of clinicians and researchers.
5. Nonpunitive followup of differences found (for example, surgeons conducted a "round-robin" of visits to each others' institutions to observe processes of care and learn from each other.
6. A heavy QI focus, with analyses emphasizing volume effects and explanations for gender differences in outcomes (body size rather than quality related) instead of focusing on bad providers.
7. Hospital identity coded in all publications.

This group discovered that outcome differences across institutions could not be explained by differences in case mix and risk factors, prompting participating surgeons and institutions to examine and often change their technqiues and systems of care. Quality of care was not found to be the factor resulting in worse outcomes for women than men having CABG surgery; instead, body size was a newly identified risk factor in accounting for differences in outcomes between the sexes.

HCFA mortality reports. The Health Care Financing Administration (HCFA) mortality reports, produced since 1987, have evolved from reporting case mix-adjusted outcomes for broad categories of care — for example, low-risk cardiac conditions — to specific diagnostic or therapeutic categories, such as CABG surgery (Hartz, Krakauer, Kuhn, and others, 1989). The outcome analyzed is mortality at various intervals postoperatively (for example, 30, 90, 180 days). The reports are constrained by reliance on International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) discharge diagnoses and other variables from discharge data abstracts (Iezzoni, 1990b).

HCFA mortality reports are made public within a short period after hospitals are notified of the results. Hospitals can adopt a defensive position with explanations of any deviations, but they do not have time to conduct meaningful clinical investigations or process improvements. The effort by hospitals tends to be focused on the external review and its conclusions about good versus bad performers. In the initial cycles of reporting, results often were prominently featured in local and national newspapers with a "bad apples" approach to differences between hospitals, differences that did not always hold up to clinical review and analysis of the next year's data. Release of hospital performance by name is a prominent characteristic of these reports that would be avoided in a QI approach.

HCFA mortality reports do use advanced multivariate techniques to maximize the use of available data from the uniform hospital discharge data set. It remains to be seen whether the potential benefits of identifying outlier hospitals and of informing purchasers can be reconciled to the risk of misidentifying hospitals that perform acceptably.

New York State cardiac surgery analysis. Another analysis of CABG surgery outcomes demonstrates features of effective quality review and also some of the pitfalls of external efforts.

The clinical variables of interest were defined by a State-wide group of active clinicians (a cardiac surgery advisory committee that studies both cardiac surgery and coronary angioplasty). Data collection was prospective using a simple two-page form, and staff of the clinicians involved performed the actual data collection. Information was fed back to the clinicians who had onsite software available to enter data and analyze their own observed and expected performances. Thus hospitals had the opportunity to examine outcomes and seek improvements if needed.

Yet the data released in 1990 in conjunction with a publication on the 1989 findings (Hannan, Kilburn, O'Donnell, and others, 1990) had many of the features of a HCFA mortality release. There was much focus on hospitals with "bad performance" in local and national newspapers, with hospitals adopting primarily defensive positions because significant internal analysis and process improvement efforts were not possible between the time of hospital notification and release of the data. Also, several of the hospitals with the worst performances in the data released in 1990 had good results in the 1989 data and vice versa.

When contrasted, most elements of the Northern New England Cardiovascular Disease Study Group and the New York State cardiac surgery efforts are similar, suggesting that both could be effective methods for improving outcomes. However, the New England effort had more of the features commonly associated with QI approaches —for example, a focus on joint examination of processes, with cross-hospital analyses of the reasons for outcome differences and the processes associated with those differences. The New York effort released the hospital name along with the performance data.

Philadelphia CABG analysis. Another CABG surgery outcome analysis illustrates the fine line between CQI approaches and well-designed research with feedback. The Philadelphia analysis at five teaching hospitals used a retrospective method to examine CABG mortality rates (Williams, Nash, and Goldfarb, 1991). While not necessarily developed as a QI effort, it was a cooperative study, and data were shared with the five hospitals whose outcomes were analyzed well before public release. The results were listed individually but in coded form, unlike the HCFA and New York State reports.

Barriers to Improvement

Other key questions are "which methods have health care executives used to identify barriers to improvement," and "which strategies have they developed for removing these barriers?"

Again, the literature does not provide hard evidence, but demonstrations, case studies, and opinions suggest some general themes of how barriers are reduced. The themes include decentralized decisionmaking, education in CQI approaches and principles of behavior (Berwick, 1989; Laffel and Blumenthal, 1989), and clinically robust quality information approaches such as application of outcomes measurements (Tarlov, Ware, Greenfield, and others, 1989).

Organizational Decisionmaking

The question of how quality information affects organizational decisionmaking is complex and more an issue of the management of institutions than an "information issue." Themes from the literature suggest four features of quality information use that maximize effects on managerial decisionmaking: (1) integration of clinical and administrative efforts, (2) incorporation of meaningful clinical performance (process and outcome) information into strategic planning, (3) close linkages between internal quality review groups (e.g., QA staff) and clinical leaders, and (4) nonpunitive, internally focused analysis of processes.

Time-Oriented Data

The use of data displayed over time has been addressed in many of the previous sections and examples. For example, the Northern New England, HCFA, New York State, and Philadelphia analyses of CABG surgery outcomes all incorporated time-oriented data analyses. Many of the internally focused systems for analyzing severity-adjusted outcomes (APACHE, MedisGroups) also incorporate the routine ability to analyze performance over time as well as across institutions.

In typical QA and QI analyses of such data, the focus is generally similar. Time-oriented data in both QI and QA help confirm whether a deviation is "real"—that is, reproducible and not a statistical artifact—and followup data over time help assess the effectiveness of interventions.

However, in formal CQI, use of quality control tools organizes data in somewhat different ways. Control charts organize data to determine if the occurrence of adverse events is random (due to "common cause" problems where overall improvements in the system lead to a new level of performance, regardless of the level of performance) versus nonrandom over time. The latter are due to "special causes"; eliminating the special occurrence is the first goal, and "tampering" with the overall system is to be avoided. Furthermore, performance within expected bounds is not a sufficient goal in QI; the QI philosophy is continuous improvement until no more improvements are possible.

Quality Information and Clinical Decisionmaking

A variety of applications of quality information directly affect clinical decisionmaking. They include critical pathways, case maps, algorithms, and case management, where there is organized effort to "design in" a standardized, preplanned set of decisions, as well as information feedback to clinicians to help them fine tune their decisionmaking for specified patient subgroups.

Outcomes management and severity of illness systems provide information to clinicians to guide their choices more generally (O'Connor, Plume, Olmstead, and others, 1991), while decision support systems help them process and assess complex information. Most traditional QA information uses provide feedback to clinicians on past decisions, rather than guide future decisionmaking.

Case Study: APACHE System

For a number of reasons, the APACHE approach (whether version I, II, or III) is a model for use of severity-adjusted outcomes in managing care (Knaus, Draper, Wagner, and Zimmerman, 1986). The core tool, severity adjustment of outcomes in a specific setting (the intensive care unit —ICU) with the APACHE scoring system, is clinically sensible and scientifically validated.

The latest implementation through the proprietary APACHE III ICU Management System provides data collection and analysis systems to "wire" an ICU to monitor patient severity, expected outcomes, and therapeutic needs on a day-to-day basis to guide clinical decisionmaking. The intent is that the clinician can use the daily information to estimate prognosis and to make some of the key decisions in hospital health care: should this patient continue to receive intensive care, is the expected benefit of ICU care sufficient, or should another patient be treated in that bed?

Time-oriented analysis of the same data in comparison with expected outcomes from the APACHE mortality model also tells an institution whether its overall or condition-specific performance for patients receiving intensive care is on target.

Clinical Information Systems

Many of the most effective clinical information systems provide active use of quality information to affect clinical decisionmaking (see the paper by Coltin and Aronow, in this volume). For example, the Regenstrief, TMR, STOR, and COSTAR systems are comprehensive ambulatory care data systems, with inpatient links, that can feed back process information to clinicians and affect their clinical decisions, through either broad feedback or specific reminders (Garrett, Hammond, and Stead, 1986).

The HELP system, developed at LDS Hospital in Salt Lake City, UT, is a model for a hospital information system that directly affects clinical decisionmaking, more through concurrent feedback on clinical actions than through respective analysis of typical quality information.

Quality Information and TQM by Institutions

While many of the potential uses of information in in health care TQM have yet to be fully implemented, there are models for use of outcomes and process information in the three domains of TQM: quality planning, cross-functional management, and process improvement through individual and team efforts (Kuperman, James, Jacobson, and Gardner, 1991). Crossing these domains is the use of benchmarking of processes or outcomes across institutions. The Malcolm Baldrige National Quality Award (1991) criteria for the category of "Information and Analysis" look very different from existing QA-oriented programs. The award criteria focus on information reflecting the process of care and how data are analyzed to promote the organization's objectives, rather than to make judgments about individual performance or problem areas alone.

The Baldrige criteria explicitly include components relating to information use and emphasize evidence of actual use rather than capacity.

The literature to date include no experimental evidence on the effectiveness or costs in health care of following all or components of the Baldrige Award criteria for information use. Case studies of QI implementations in health care focus on process improvements and QI project team efforts, with little or no reference to institutional QI information systems and their use.

Use of Quality Information by Purchasers and Patients

Purchasers of health care have become increasingly interested in health care quality. In a survey of 100 benefits managers conducted for Metropolitan Life (1990), over 60 percent responded that health care quality will become a "somewhat" or "much more" significant issue over the next 2 years. As a result, a majority of the respondents planned to develop "a more formal approach to managing health care quality. A corroborating survey of 250 hospital chief executive officers found that over 70 percent of the respondents indicated quality of care will become a key determinant of hospitals' market share during the 1990s. In addition, almost three-fourths said that third-party payers will begin tying hospital reimbursement to quality measures within the next 5 years (Johnsson, 1991).

Intuitively, cost and quality are now related in the minds of many purchasers, who believe that poor quality care is ultimately more expensive than good quality care. Although this conclusion seems obvious and rather insignificant, it in fact represents a major change in attitude from the long held assumption that more health care, and more expensive health care, equaled better health care. This shift is consistent with the themes of CQI and is driven in part by dissemination of CQI through large segments of American industry.

The relationship between cost and quality is captured in the concept of "value", defined as "necessary health care at reasonable cost" (Nash, 1991). The components of medical care "value purchasing" are described as involving definitions of provider cost and quality, measurement systems for provider cost and quality, mutually agreed upon standards, criteria for selecting providers based on clinical performance, benefit plan incentives to channel employees, and reimbursement adjustments based on demonstrated value (Couch, 1989).

The discussion that follows explores the potential change-agent role of purchasers in using information on quality of health care. Three purchaser roles are discussed: (1) health care manager, which covers the relationship between health care purchasers and health care providers; (2) information brokers, which concerns the relationship between health care purchasers and their employees, dependents, and retirees; and (3) community partners, which deals with the relationship between health care purchasers and their communities.

Purchasers as Health Care Managers

We define a purchaser of health care broadly to include private employers who self-insure or purchase health care through insurers, labor unions, public employers, and groups of employers who affiliate to purchase or influence the delivery of health care. Certainly, the ability to take on any of the following change agent roles will depend on the size and resources of a purchaser.

Pioneering health care research has been conducted over the past 15 years on such quality-related topics as small-area analysis (Wennberg, 1990), appropriateness of care (Brook and Lohr, 1987), and the relationship between volume and health care outcomes (Luft, Hunt, and Maerki, 1987). The implications of this type of research have resulted in the oft-quoted observation by former *New England Journal of Medicine* editor, Arnold S. Relman (1991), that 15–30 percent of medical and surgical procedures are not medically indicated, and an almost equal number are marginally indicated.

Continued escalation of overall and employer-based health care costs through the 1980s ensured that interest in these findings was more than academic, as purchasers raised questions about the value and quality of the care delivered to their employees, dependents, and retirees. In 1991, total employer health care costs reached an average of $3,605 per employee, more than double the amount 5 years earlier (Winslow, 1992). The fact that the results of quality of care and variations work began to appear in business-oriented publications such as *Business and Health, Business Insurance,* and the *Wall Street Journal* resulted in the transfer of knowledge from the medical world to the purchasing world.

One of the major implications of research over the past several years has been that employers should care about the quality and value of health care provided to their employees. Previously, the quality of health care had not been perceived as a concern. The assumption was that purchasers and their employees got what they paid for without much attention to what they received or how what they received related to what they paid for. Recognition that health care providers could be differentiated based on their performance, use of resources, and outcomes led to the emergence of "buy right" strategies that involved identifying the most efficient health care providers in a community and offering incentives for employees to use those providers (Traska, 1990). While conceptually clear, "buy right" is often difficult to operationalize given the lack of medical consensus on or measurement of what constitutes high quality, cost-efficient medical practice.

A key change in the relationship between health care purchasers and health care providers is the movement away from a relationship defined primarily through bill payment, to one based on a relationship between a customer (purchaser and/or patient) and a supplier (health care provider). The need for supplier focus on customer satisfaction based on continuous evaluation of needs and expectations accompanies this shift toward the CQI model (McEachen, Markens, Buchanan, and Schiff, 1991).

As health care managers, purchasers or customers have begun to think in terms of defining what they are buying, gathering information and making decisions based on standardized information, monitoring health care provider performance, and demanding accountability for results. Each of these activities, the tools used to support them, and a corporate case example are briefly described below.

Identifying health care services to be purchased. A first step in the evolving formal customer-supplier relationship is the process of defining which health care services the purchaser wishes to buy in the community. This is usually done through a process of internal discussion involving a corporate benefits staff, corporate medical department, and often an employee benefit consulting firm. When this process is formalized, the result may be a request for proposal (RFP) that is disseminated to community health care providers (Miller and Miller, 1988).

RFPs may include requests for the following types of quality-related information: staffing, credentialing, continuing medical education, and performance evaluation procedures; continuity of care; compensation and risk-sharing arrangements; utilization management; case management; development, use, and evaluation of medical guidelines; descriptions of clinical quality assessment, measurement, or improvement programs; access to care; and health promotion and health education (Longo, Bohr, Miller, and Miller, 1990).

Other types of information generated by a hospital that have been suggested to be of value to the public include: nosocomial infection rates, medication and transfusion errors, postoperative complications, percent of surgical cases during which normal tissue was removed, number of deaths within 24 hours of admission, and other similar measures of clinical performance falling in the category of "quality markers" noted earlier in this paper (Hofmann, 1990).

The next generation of RFPs focused on identifying health care providers who can treat a particular set of usually high-cost and relatively infrequent medical conditions. Often termed "centers of excellence," these are institutions with a proven track record for certain types of procedures such as organ transplants, neurologic procedures, and some types of rehabilitation. Companies such as Honeywell, Parker Hannifin, and Carlson Companies (owners of the Radisson Hotel chain), as well as many of the major insurers, have instituted these programs. The types of quality of health care data used to assess a potential center typically include utilization data, death rates, morbidity data, accreditation data, and patient selection criteria for procedures (Christensen, 1991).

Case example. The Rolscreen Company, a self-insured, privately owned manufacturer and supplier of windows (Pella), doors, sunrooms, and skylights issued one of the most innovative RFPs with respect to quality of care information (Miller and Miller, 1991). The RFP includes the following statements:

> *This RFP describes requirements for health management partners. These requirements are based on: (1) health risks and health care service utilization history of employees, non-Medicare retirees, and their dependents; (2) predicted health risks and health care service requirements of employees, non-Medicare retirees, and their dependents; (3) Rolscreen's goals and objectives,*

that is what the company expects to accomplish with its health management program; and (4) how Rolscreen hopes this initiative will positively affect community residents' health and the quality of community health care.

The RFP discusses the responsibilities of the health care manager, which include the development of a system of rigorous clinical and other quality criteria for each selective contracting service and product area (e.g., obstetrics, cardiovascular care, cancer, primary care); negotiation of service-specific selective contracting arrangements on behalf of Rolscreen with providers and/or suppliers that meet quality criteria; and development and implementation of supporting programs and services, including health risk assessment, measurement of patient satisfaction, management reporting, proactive case management, utilization management, and claims administration.

Supplier selection/certification. After preliminary information is gathered and analyzed through an RFP process, the purchaser may gather additional information about the quality of health care prior to selection. This may involve on-site visits to health care providers to physically inspect the premises and collection or verification of information from government agencies such as medical licensure boards, health departments, or insurance commissions.

Increasingly, private accrediting or standard-setting bodies such as the JCAHO, the National Committee for Quality Assurance, the Utilization Review Accreditation Commission, and other programs are positioning themselves to formally gather data on the quality and outcomes of care provided by health care suppliers. These bodies can then assure health care purchasers that certain standards have been met by suppliers, thereby negating the need for duplicative quality of care information collection.

Case example. Beginning January 1, 1990, Xerox Corporation initiated Healthlink, an employee benefits program that contracted with six managed care organizations after an exhaustive review process which included questions on every aspect of the plan's operations, oral presentations by competitors, and site visits. The six companies serve as "network coordinators" and are responsible for evaluating the performance of individual plans within their network (Traska, 1990a, 1990b). With reference to quality of health care, Xerox requires that plans be accredited by the National Committee for Quality Assurance, conducts consumer satisfaction surveys, and collects preliminary clinical indicator quality data in the prevention area with respect to childhood immunizations and cancer screening.

Supplier contracting. Some argue that guidelines governing a supplier-customer relationship with regard to the quality of health care delivered should be incorporated into the contractual language between a health plan and a purchaser. In arguing for a pluralistic model of medical guidelines development, Havighurst (1991) notes that such pluralism allows private health care plans to be customized to the particular needs of the purchaser.

Case example. As part of a quality-driven purchasing program, the Health Policy Corporation of Iowa, an 87-member coalition consisting predominantly of employers throughout Iowa, developed a "recommended model agreement" that outlined model contractual specifications and accountabilities for purchasers doing business with health plans and other suppliers (Health Policy Corporation of Iowa, 1991). Included in the model agreement are sections that deal with the following quality of health care topics: data, information, and reporting; patient satisfaction; quality of care; CQI; utilization management; case management; health promotion and wellness; and provider performance objectives.

Interestingly, State legislatures are beginning to codify adherence to quality of care guidelines as a prerequisite to supplier receipt of expenditures for public health programs. For example, legislation passed in 1991 in Florida requires that hospitals receiving public funds for maternity care must specify the guidelines that are applied prior to the performance of certain cesarean section deliveries. In Rhode Island, a legislatively mandated committee is responsible for recommending a set of medical practice standards and treatment protocols to be certified by the legislature and used by physicians as an affirmative defense in medical malpractice, by employers in a value purchasing process, and by State legislators as a possible means of determining reimbursement policies for the State Medicaid program (Quality Resource Center, 1992a, 1992b, 1992c).

Supplier performance monitoring/accountability. Once the contract between customer and supplier is established, the relationship moves into one of monitoring performance and measuring accountability against standards. As described earlier,

baseline information is often collected in the RFP process. Information collection related to the quality of care delivered could include such topics as the frequency and/or length of stay for procedures that have a wide variation nationally (e.g., laminectomy, hysterectomy, CABG surgery, cesarean sections); adverse event occurrences that may indicate compromised care (hospital readmissions, premature deliveries, and so forth); and indicators related to preventive care (immunization, mammograms, pap smears). In addition, purchasers are interested in the longer term functional outcomes of care delivered by suppliers. Under the auspices of the Managed Health Care Association, employers are working with health plans to collect and pool outcomes-related data on angina, asthma, and low back pain. This will allow purchasers to follow individuals over time to learn who benefits from treatment and what costs and qualitative differences exist among treatment settings (Interstudy, 1992).

Purchasers also are interested in the satisfaction of their employees, dependents, and retirees regarding interaction with health care providers. Proponents of involving consumers in judging quality of care make the following arguments: (1) consumers' assessments of quality predict their behavior in the market; (2) consumers need not be clinical experts to provide accurate information about quality; (3) data from patients are less expensive than other data sources (medical record audits, data base searches); and (4) data from consumers provide information not otherwise available (Davies and Ware, 1988).

Case example. The Bay Area Business Group on Health, a coalition of large employers in the San Francisco area, conducted an employee medical plan satisfaction survey on behalf of six member companies in 1990. A total of 163 health plans nationwide were evaluated by 14,437 respondents representing a 46 percent response rate. On a plan-by-plan basis, the study revealed dramatic differences with respect to employee satisfaction. The plan with the highest rating in the area of physician care had 97 percent satisfied customers; fewer than 50 percent of the respondents in the lowest rated plan were satisfied with physician care. When asked about how likely they were to switch to another plan, employee's responses ranged from a high of nearly 40 percent who were likely to switch to a low of 4 percent (Bay Area Business Group on Health, 1991).

Building long-term partnerships. Although implied in many of the roles described in preceding sections, particular mention should be made of purchaser interest in building long-term relationships with a relatively small number of suppliers based on cost-effectiveness and quality. Many purchasers have been overwhelmed by the explosion of vendors selling services for every aspect of health care. Others reduce the number of suppliers as part of their TQM efforts.

Case example. Bull Information Systems, a high technology computer company, and Harvard Community Health Plan, a Boston-based staff and group health maintenance organization (HMO), are collaborating on a long-term partnership project with a focus on reducing the employee's risks for cardiovascular and other lifestyle-affected health problems. The project will involve several steps including a health risk appraisal administered to all employees, analysis of the data to identify problem areas related to lifestyle factors, a report on suggested interventions to improve health outcomes in those areas, and implementation of the interventions beginning in 1993 (Quality Resource Center, 1992a).

Information Brokers

Second, purchasers may assume a major role as brokers of information between suppliers and consumers of care (Friedman, 1992). Building on past efforts involving worksite wellness and health prevention and education, purchasers are increasingly interested in arming their employees with information that can be used in decisionmaking about health care providers or alternative treatment options.

The role of information broker can take many forms. In some cases, the purchaser may simply bring information to the attention of employees through consumer-oriented newsletters they purchase from a growing number of health care information vendors (Quality Resource Center Update, 1991). Other corporate communication vehicles include posters, bulletin boards, company newspapers, videos, kiosks, computer programs, mailings, closed circuit television, or face-to-face meetings (Ailes, 1991).

Corporate information can be either generic (information about hospitals, HMOs, or physicians) or condition-specific. Over 30 States have mandated the development of public domain health data sets, with many of those requiring hospitals to submit an

abstract for each discharge from their facility (Terry and Epstein, 1992). For example, the Quaker Oats Company has used data from the Illinois Health Care Cost Containment Board and repackaged it into a series of booklets comparing hospital prices on selected inpatient and outpatient procedures (Quaker Oats Company, 1990). Given that most State data collection efforts currently focus on financial and utilization information, most public domain data have not yet included information about the quality of health care. As States incorporate quality measurement systems into their collection efforts, this type of information will be released to health care information brokers.

In other cases, the purchaser may participate in or design an information campaign targeting employees, dependents, and retirees around a specific medical condition or diagnosis such as prenatal care (Cronin and Hartman, 1989), depression (Vaccaro, 1991), cesarean sections (Cronin and Koepke, 1991a), or alcohol abuse (Koepke, 1991).

Special mention should be made of the role of health care coalitions as health care information brokers. For example, the Health Care Purchasers Association of Puget Sound (1991) published a 32-page consumer guide that includes sections on doctors, hospitals, HMOs, preferred provider organizations, medical quality, surgery, emergency care, maternity care, diagnostic tests and X-rays, medications, the cost of care, and employee benefits. The Houston Area Health Care Coalition has published consumer-oriented guides on mental health and maternity care. The Pennsylvania Health Care Cost Containment Commission publication of hospital performance data was prompted by business interests in "buy right" health care purchasing, though the commission itself is legislatively mandated (Shanahan 1991). Finally, coalitions in Florida, St. Louis, and Pennsylvania have expressed interest in Health Pages, a consumer oriented magazine that provides price and service information on doctors, hospitals, managed care plans, nursing homes, and other medical professionals in those areas (Schneider, 1991).

Community Partners

A third change agent role that purchasers can play with regard to health care quality is at the community level. Increasingly purchasers are viewing their relationships with suppliers not only in the context of contractual relationships but also in terms of the need to improve the health of the community. Partnering in this regard can take a number of different approaches.

Community-level aggregate data gathering. Several health care coalitions are exploring the design and implementation of a community health management information system. Using the same technology found in the financial services industry (for example, bank teller machines, credit cards) and grant monies from the John A. Hartford Foundation, coalitions in Iowa, Memphis, and Seattle are designing business plans that will involve specifications for both a community-level data base (patient profiles, provider and employer profiles, community level health statistics, and so forth) and a transaction processing role (eligibility analysis for health care providers to establish patient enrollment status, available coverage, and utilization review requirements) (Quality Resource Center, 1992a).

Improving community focus on health quality problems. The National Partnership to Improve Maternal and Child Health, convenes local leaders in commununities nationwide to create dialog around problems and solutions related to maternal and child health. The meetings have brought together community leaders, who previously had rarely communicated, to achieve commonly accepted goals (Bacon, 1991)

Community-level CQI. In Kingsport, TN, Milwaukee, and Chicago, hospital and business leaders have joined forces to apply QI principles to such issues as coordinating care, managing back pain cases, reducing hospital readmissions, and reducing claims denials by utilization review firms (Anderson, 1991).

Public Policy Initiatives

Employers and health care coalitions have been at the forefront of efforts to collect and analyze hospital and physician data by State health care data organizations. In addition, national employer organizations such as the National Association of Manufacturers and the Washington Business Group on Health have been supportive of increased public funding for research on QI and measurement.

One should not overestimate the simplicity or likelihood of success of relationships at the community level. In some communities, the same types of initiatives listed above lead to divisiveness, conflict, or lack of interest.

Patients as Agents for QI and QA

The physician-patient relationship is ultimately the heart of the health care delivery system. The relationship takes on mythic proportions that have been described as a "sacred trust" (Friedman, 1992). Indeed most arguments for or against doing or not doing almost anything in medicine are made on behalf of the patient.

The etymology of the words patient and consumer is relevant. *Webster's New World Dictionary of American English* (1990) defines patient as "One who or that which is passively affected; a person who is under medical treatment." The word is derived from the Latin *pati,* which means to suffer. In contrast, "consumer" is defined as "the buyer or user of commodities and services," and its Latin derivative, *sumere,* means to take up. Having been socialized to be "passively affected," do patients have the capacity and interest to "take up" information about the health care system and be agents of change regarding the quality of care delivered to them and their families?

A review of recent survey results with regard to patients' views on the quality of health care they receive indicates that most people are satisfied with the quality of their own health care but perceive that the overall health care system is in turmoil (Employee Benefits Research Institute, 1991; Mellman, 1992).

Choosing a Health Care Provider

How do consumers choose their health care providers? A review of the literature indicates that relatively little research has been done on this issue. Patient intuition and subjective assessment based on such factors as personal impressions, proximity, and limited knowledge about their performance outcomes are often cited as the criteria underlying physician selection (Daley, Gertman, and Delbanco, 1988). Steiber (1988) reported the results of a national poll conducted for *Hospitals* magazine, in which consumer satisfaction was found to be influenced more by concern shown for the patient than by clinical care. For example, cleanliness and visiting policies were two factors that patients rate at the highest satisfaction levels. In a survey of 1,000 employees, a doctor's reputation was the chief criterion in the selection of a physician (Managed Care: The Employee Perspective, 1991).

Given that there is little or no information about physicians available to the average patient, it is not surprising that informal and nonscientific selection criteria are used by patients. In contrast, in recent years, limited information has been made available to the public about hospital quality measured in terms of hospital volume and, in some cases, patient outcomes. As described earlier in this paper, since 1987 data have been released by the Federal Government regarding hospital mortality rates for Medicare patients with selected diagnoses (Health Care Financing Administration, 1987).

Citing the potential for use of this type of information in patients' choice of hospital, researchers have estimated the influence of quality, charges, ownership, or distance on the choice of hospital for patients with seven surgical procedures and five medical diagnoses in hospitals in California in 1983 (Luft, Garnick, Mark, and others, 1990). Though the research was conducted prior to the release of much public data, the authors were interested in whether hospital choice decisions were already "quality-sensitive" and therefore more readily able to incorporate newly emerging public data. They found that hospital quality does play an important role in hospital choice. They assume, however, that this reflects primarily physician referral patterns, perhaps influenced by patient concerns about differences in quality across hospitals. They conclude that rather than focusing on the public to use complex information effectively, detailed quality of care information should be made available to physicians, while patients should be made aware that quality may vary substantially between hospitals.

Despite the availability of several years of Federal and State public domain health information, there is no known research evaluating its direct usefulness to consumers of health care.

The Congressional Office of Technology Assessment released a landmark study in 1988 evaluating the reliability and validity of indicators of medical care quality that consumers could use to choose physicians and hospitals (Office of Technology Assessment, 1988) The 10 indicators included hospital mortality rates, adverse events that affect patients (e.g., nosocomial infections), formal disciplinary actions taken against physicians by State medical boards, PRO-recommended sanctions, malpractice compensation, evaluation of physician's performance in caring for a particular condition (for example, hypertension screening and management),

volume of hospital and physician services, scope of hospital services, physician specialization, and patients' assessments of their care. In a 1990 summary of their findings, the authors conclude that none of the indicators examined provides definitive information on the quality of a hospital or physician across the range of medical care (Sisk, Dougherty, Ehrenhalft, and others, 1990). They also made the following three recommendations:

- Organizations and individuals can use some of the indicators as screens to flag areas that merit further examination.
- Information about unacceptable care justifies more attention than information that ranks good quality providers because of the greater risks posed by poor quality and the current state of QA techniques.
- Consumers would be well advised to combine information from more that one indicator and for more than 1 year to increase the likelihood that the information is accurate.

Interestingly, the popular media are increasingly targeting information to health care consumers. The number of consumer-oriented health care columns or newspaper or magazine sections on health has increased dramatically in the last 10 years. One trend is that of regional magazines conducting surveys of physicians or other health care providers and asking them whom they would recommend. Survey results published in *The Washingtonian* magazine are typical (Stevens, 1991). Over 3,000 physicians in the Washington-Baltimore area were asked to name specialists and hospitals to whom they would send members of their families for particular kinds of treatment. Published results from the 825 physicians who responded included the names of 580 "top Washington physicians" arranged by specialty area.

Ongoing Evaluation of Health Care Providers

If information on consumer choice of health care providers is limited, even less is known about how consumers evaluate their care on an ongoing basis and how, when, and why they decide to switch providers. The lack of knowledge is particularly acute in traditional fee-for-service medicine, where consumers have total choice in whom they see and how often. Given the lack of feedback loops between patients, physicians, and hospitals, there are perhaps only a small number of ways traditional fee-for-service health care providers know how their performance has been evaluated by patients:

- The patient leaves the provider. In many cases, the provider may not even know that a patient has left the practice given the lack of process and systems to "terminate" a relationship. Requests for copies of medical records may be one indication, change of address notifications another. In most cases, the provider probably does not know why the patient has left the practice, thus negating the opportunity for learning.
- The patient tells the provider he or she is leaving the practice or choosing another hospital and the reasons why.
- The patient sues the physician or complains to a State medical licensing board, a peer review organization, or other public agency.

As discussed above with reference to health care purchasers, health care providers also are discovering the importance of viewing their patients as "customers." Market research on who one's patients are, where they come from, why they come to a particular provider, how the provider ranks among competing providers, and how much of the market a provider controls are all factors that could be pursued (Omachonu, 1990).

Increasingly, consumers are finding themselves in managed care health plans. While difficult to describe succinctly, most managed care integrates the financing and delivery of health care services and includes the following four basic elements: (1) arrangements with selected providers to furnish comprehensive benefits; (2) selection standards for providers; (3) formal programs for ongoing QA and utilization review; and (4) significant financial incentives for members to use providers and procedures associated with the plan (Hoy, Curtis, and Rice, 1991).

Given that individuals enrolled in managed care can vote with their feet regarding which providers they choose and when they choose them, they offer a natural setting for evaluating health care consumer choices. The fact that the plans usually capture some level of detail about the patient-plan-physician encounter enables them to better target a population for studies on such issues as:

- *Enrollment/disenrollment.* Why do consumers enroll in plans? Why do they leave?
- *Use of providers in-network vs. out-of-network or switching health care providers in-network.* How do consumers evaluate when to use a plan sponsor and when to go out of plan? How do consumers choose providers within a plan? Why do they switch to another provider within a plan?
- *Utilization review.* Under most managed care arrangements, the physician is required to contact an intermediary regarding the treatment plan for the patient. How do patients respond to a variety of utilization review requirements? Does it affect physician-switching behavior? Are patients more informed about their treatment alternatives after a utilization review process?
- *Consumer satisfaction surveys.* As previously mentioned, plan members can be directly queried about their satisfaction with an overall plan and its individual physicians and other providers.

Participation in Community-Wide Activities

In addition to consumers as quality of care change agents in their choice and ongoing evaluation of providers, their participation in community-wide activities can provide them access to health care policy decisionmaking regarding the quality of care. As previously discussed with regard to health care purchasers, consumer participation in health care related boards, committees, and other relevant organizations can bring the perspective of the ultimate end-user: the patient. Organizations such as the American Association of Retired Persons (AARP) and others have developed programs to help train consumers to fulfill this role. For example, AARP sponsors the Citizen Advocacy Center, which is a support center for public members of health care regulatory and governing boards such as Medicare Peer Review Organizations and medical, nursing, and nursing home administrator licensing boards.

Information Use by Purchasers and Patients

There is, and will continue to be, tension between customers and suppliers over whether to "act now" using quality of health care information that is less than perfect and may be clinically questionable or to wait to act until more meaningful data are available. The reality of an increasingly informed and involved purchaser and consumer community dictates that "no action" is probably not an option. There also seems to be a customer willingness to work with the supplier community (and perhaps the research community) in moving the development and use of quality information forward, perhaps by applying the principles of CQI to the process itself. Given the newness of many of these activities, there is an opportunity for the Agency for Health Care Policy and Research to fund research into much of what is being tried by purchasers and groups of purchasers.

Many of the role changes described in preceding sections of this paper assume a fundamental change in the practice of medicine with regard to the quantity of information made available to measure performance. One cannot underestimate the degree of corporate culture and behavior change this will entail, which will engender resistance, efforts to co-opt, lawsuits, and politics. This also suggests that research is needed to enhance understanding of cultural and behavioral change on the part of health care providers which may involve the disciplines of sociology, psychology, organizational development, anthropology, and communications.

At the same time, an equally fundamental change is assumed in the role of "purchasers" from "bill payers" to "health care managers" and from "patients" to "consumers." It is not yet clear what the parameters of these roles will be or how much resistance there will be to assuming them. There is a certain comfort in not being responsible for one's health or the health of others. In addition to the disciplines mentioned previously, research that borrows from the field of business administration may be helpful (product design, marketing, organizational psychology, customer satisfaction, and so forth).

The employer community is beginning to define a vision of the future health care delivery system it desires. Termed "organized systems of care," the system represents the next generation of managed care. While the components of the delivery system are still being developed, in-house systems of quality control and external demands for accountability will be fundamental features. Some of the elements of these systems are incorporated into current state-of-the-art purchaser practices. The opportunity exists to critically study these elements to learn whether they are valid and reliable measures of provider performance.

Research Questions

Provider (Institution and Clinician) Uses of Quality Information

1. Very little of the published literature on use of information in QI and QA meets even the most liberal rules of evidence. A key question is: What are the efficacy and effectiveness of various models for QI and QA efforts when scientifically and objectively measured?
2. What is the diagnostic accuracy (sensitivity and specificity) of various quality measures as applied by institutions in their quality related efforts? Measurement using an objective standard is a criterion for diagnostic maneuver assessments and is lacking in assessment of the measures used in quality information generation.
3. What are the relative benefits of various components of both QI and QA? For example, the benefit of benchmarking information is a key QI issue; the benefit of components such as medical record review is critical for typical QA.
4. What effect do comprehensive models of quality information use (such as those integrating outcomes management information with formal TQM) for QI have on the decisionmaking and processes of institutions?
5. How accurate are classifications of providers or institutions regarding quality of care based on various types of quality information (e.g., severity-adjusted outcomes, clinical indicator rates, meeting standards for the process of care)?

Customer (Purchaser and Patient) Uses of Quality Information

1. A number of questions relate to "buy right" programs: How have they been implemented? What have been the quality measures used to select providers? How valid and reliable are those measures? How have employees, dependents, and retirees responded to incentives? How has the health care community responded to the incentives? Have the programs resulted in a change in the delivery of health care in the community? How do we know?
2. How valid and reliable are the quality measures currently being used by purchasers to select and monitor health care providers with reference to the provider's ultimate performance? How do these measures differ in various components of care delivery (hospital, physician, nursing, mental health, highly specialized "centers of excellence," personal care, and so forth)?
3. What are the pros and cons of delegating quality of care monitoring to external bodies (such as government agencies, private accrediting bodies)? Is there a taxonomy of assigned responsibility for health care quality that extends from the patient to the payer, to the health care provider, to the government?
4. What are the legal, political, clinical, and ethical implications of including quality of care in contractual language?
5. What elements of customer satisfaction are valid and reliable predictors of the technical quality of care? The process of care?
6. What are the elements of successful and unsuccessful "partnerships" between health care customers and suppliers? Do partnerships improve the quality of care delivered in a community? How do we know?
7. What methods of information brokering are specifically effective in educating employees, dependents, or retirees? Does information dissemination lead to changed patient/consumer behavior as indicated by different utilization patterns, cost changes, and/or quality of care measures?
8. How do patients choose, monitor, and terminate their relationship with the health care delivery system? What are the relative roles of physicians, friends and family, media, publicly available data, other patients, employers and insurers, advertising, and other factors?
9. Is there a taxonomy of patients that relates to the intensity and type of information needed to make health care decisions (that is, from no information to every possible piece of information)?
10. How do different types of health care plans (fee-for-service vs. managed indemnity vs. different types of HMOs) affect patient decisionmaking and delivery of health care?
11. What are the successful models of turning health care data into health care information? How do we know they are successful? How is the information used?

12. How do/should emerging technologies affect patient decisionmaking (interactive video discs, real-time computer-assisted systems such as APACHE)?

13. How does consumer/patient participation on health care boards, committees, and other organizations affect the deliberations and decisions of those bodies and patient care?

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What Is Quality Improvement: A Report from the Field

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Introduction

This paper concerns quality improvement in the field. I am writing from the vantage point of someone who is working in the field, and I will explain what quality improvement (QI) is and where research is needed.

First, many of the best and brightest health care providers are working very hard to try to find better ways to deliver health care by harnessing QI theories and methods and putting them to work in hospitals, clinics, and health maintenance organizations (HMOs).

Those championing QI have used many different terms—such as continuous quality improvement (CQI), continual improvement, total quality management, and organization-wide improvement—to describe a broad theoretical knowledge base and an associated set of practices, skills, tools, and techniques. Some basics of QI in health care involve:

- Understanding and meeting the recognized and unrecognized needs and expectations of patients and other purchasers of health care.
- Understanding what quality means from the viewpoint of patients, families, and other purchasers of health care.
- Leading health care organizations seeking to meet needs and expectations through systematic efforts to improve quality and value.
- Understanding that all health care is provided in systems, medical procedures are interdependent with the delivery system, and knowledge of these interdependencies is fundamental to improvement.
- Understanding the core patient care delivery process and related supporting processes in the settings where care is delivered.
- Evaluating variation in patient case-mix, delivery processes, and outcomes as a guide to taking economical action on processes and outcomes.
- Measuring the quality and value of health care using multiple indicators based on knowledge of the systems, "customers," and underlying social need for health and health care.
- Taking action for improvement (that is, planned improvement trials) that simultaneously build knowledge on how to take action effectively.
- Involving the energies of everyone in the health care organization for the task of never-ending improvement.

Although these ideas are not new, QI explicitly grounded in these theories is new to health care, and interest is mushrooming. Numerous articles and books are educating physicians and health professionals about QI ideas and practice. Moreover, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has clearly stated its intention to begin emphasizing continual improvement of patient care as the main emphasis of health care organizations.

On the other hand, there are QI skeptics, both providers and researchers, who have seen countless fads come and go. They have seen old wine put into new bottles, and they ask: What is QI? Is there anything different between QI and quality assurance except the swap of a capital I for a capital A? Does QI work? How? What is QI research? Is it worth doing?

These are fair questions, and they demand good answers. I propose to give you some answers, but rather than tell you what I personally view as the answers, I will take a different approach that I will call QAE. This stands for "questions and answers from experts."

Questions and Answers from Experts

In preparing this paper I interviewed two expert QI practitioners who have dedicated the past 5 years of their lives to work on quality. One is Paul

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Batalden, a physician who is the senior quality officer of Hospital Corporation of America (HCA). The other is Chip Caldwell, president and chief executive officer (CEO) of West Paces Ferry Hospital. I asked each of them four questions:

1. What is the essence of QI?
2. What is your QI work?
3. What have you accomplished?
4. How could QI research be put to work for you?

What is the essence of QI?

Batalden: The essence of QI work is that it is done from a different knowledge base than we have used to make improvement before. An example is smallpox. We knew the basic science of smallpox—the virology, the immunology, and the pathophysiology—decades before we were able to effectively apply that knowledge. In fact, we were within a hair's breadth of eliminating smallpox in Bangladesh when the Muslim festival of Eid occurred. The entire population packed up their belongings and visited their birth homes, much to the surprise and chagrin of the public health workers. They lacked knowledge of the system of disease and the sources of variation. This limited the effectiveness of their work. As a result, smallpox persisted for 3 more years in Bangladesh.

The knowledge that is the essence of QI and CQI includes the traditional discipline-specific knowledge of health care complemented by knowledge of the system; knowledge of variation and the way it manifests itself in that system; knowledge of psychology, particularly the intrinsic motivation that is present within the system and can be made available for improvement with wise management; and finally, a theory or approach to taking action that simultaneously builds further knowledge of the system and its operations.

Thus, the essence of CQI has to do with a different underlying knowledge system than the knowledge system that supports our traditional efforts at improvement.

Caldwell: People have tried to make QI a mystery. The first time I saw the Deming cycle, it struck me as the purest integration of marketing and operations I had ever seen. I remember the first time I talked to Dr. Tommie Frist, the CEO of HCA, about the Deming cycle and QI. He said: "How can anybody be against this? It's just good management."

I see QI as a framework for understanding the need to provide health care and to interpret and reinterpret customer needs as they change over time. This enables you to make continual improvement in processes and services to meet these changing needs. In short, QI is nothing more than a framework to achieve what you are in business to do.

What is your QI work?

Batalden: I see myself as a student. My job is to study the basic knowledge of improvement and to work together with a wide range of others to test applications of that knowledge in the daily work of health care and hospitals. As such, I find myself continually walking between the world of theory and the world of practice and involved in a never-ending effort to simplify and clean up the ways in which I communicate about that journey between theory and practice.

Caldwell: First, I use QI tools to learn which businesses the hospital should be in. This means synthesizing all the myriad customers and their sometimes conflicting needs. Second, once we have created a new business or service—such as the Diabetes Center or the Sports Medicine Center—I supervise it using QI tools. I have the managers of the services use the same QI tools so they can tell me how well they are doing.

Third, I help ensure that we have an empowered work force. The challenge is to create and monitor an environment where QI tools are used by everyone. To do this we have worked to create a shared vision, and we have developed a set of 42 integrated, hospital-wide measures that link with 400 measures at the department level. These measures give us a compass to see where we are and if we are heading in the right direction. With regard to empowerment, it is irresponsible for management to withhold the power from individuals and teams to make improvements. If management wants to empower the work force, then we must educate them to recognize whether a proposed change is good or bad for the whole hospital. That is, employees need criteria they can use to tell if a change is really an improvement for the hospital as a whole.

Fourth, I am working to build a care delivery system that self-improves. We are working with

physicians and other clinicians to make repeated improvements in areas like maternity care and cardiac care and for chronic problems such as diabetes. For example, we are trying to develop a system for providing diabetes care that brings annual health care costs down while simultaneously improving outcomes.

What have you accomplished?

Batalden: Not very much, in relation to the task. I have had the privilege of identifying and working with a small number of colleagues in Nashville and a larger number of dedicated health leaders in hospitals and health systems across the country. Whatever I have accomplished has been in conjunction with and through them. Here are some of our achievements:

1. We have developed a family of measures that can be used by health care leaders to measure the judgments of quality made by patients and their families, communities, employees, and payers. Leaders can use these customer-based measures of quality to improve services.
2. We have developed an approach for health care leaders to introduce this new knowledge (that is, continual improvement) and an associated curriculum of learning opportunities to support those leaders.
3. We have shared our work broadly with graduate programs in health administration, medicine, and nursing at places such as Duke University and the University of Toronto.
4. We have helped the JCAHO develop an understanding of continual improvement.
5. We have worked with nearly 100 hospitals and health care systems inside and outside of HCA and the Henry Ford Health System to help them make many improvements.

Caldwell: These are a few of my hospital's accomplishments.

1. We have cut cesarean section rates from 22 percent to under 12 percent in 3 years.
2. We have increased our efficiency in treating chest pain (that is, admitting patients with actual myocardial infarction (MI) as opposed to patients with non-MI chest pain) from 28 percent to 68 percent. This saved one of our customers, Prucare, $330,000 in 1 year.
3. We have reduced the percentage of non-registered nursing duties that nurses perform from 40 percent to 24 percent and have saved $250,000 annually.
4. We have cut turnaround time in the operating room by 25 percent, thereby cutting the amount of time that patients have to wait in the holding area from 23 to 6 minutes.
5. We have created the expectation among our medical staff that any new service we choose to offer will be run very well and will be top quality. For those interested in dollars, we have increased annual operating margins from $9 million to $20 million.

How could QI research be put to work for you?

Batalden: Helpful research requires careful understanding of the context to which it will be applied. Therefore, QI research will be most helpful if it is undertaken with an understanding of theory and the realities facing leaders who are trying to apply that theory.

Given those requirements and caveats, research in these areas could be useful:

1. New knowledge about organizational change.
2. Behavior of health care processes and systems.
3. Underlying needs and drivers of quality assessments by patients and their families, communities, providers, and payers.
4. More effective means of teaching scientific and statistical thinking to health workers.
5. More effective recognition mechanisms for the discernment of barriers to joy and pride in work.
6. Balanced measures of provider effectiveness in improving health risk and health status.
7. Ways of reducing the costs of applying CQI knowledge into the daily work of ordinary nurses, doctors, and hospitals and other health care settings.
8. Better information on ways to educate health workers about measurement—for confirming that we are doing and improving as we intend, and for learning how we can make even more improvements in our processes and systems of work.

Caldwell: I will answer this question with my wish list. I wish we had:

1. More knowledge on how to make quality deployment throughout my hospital easier.
2. An automated medical information system to link all the needed data together.
3. More "time" data, (that is, showing variability in how long it takes to do things) to complement our financial data (that is, showing how much things cost).
4. Methods for working with our suppliers to reduce the total costs of services we provide; for example, research on how to reduce supply costs in our most labor intensive areas.
5. Knowledge about better employee compensation systems.
6. Better methods for teaching employees how to use QI tools to improve their daily work.
7. Benchmarking systems to help us learn how to provide services more effectively.
8. Data systems that employers could use to accurately identify providers who deliver the best and most efficient care for a population of patients.
9. Research results on care delivery models for the top five diagnoses in the Nation that show how to make health status and efficiency improvements.
10. Research on how to develop community models for health care delivery that would enable all providers to work together to improve quality and cut costs (for example, 20 hospitals in Atlanta are working together to find safe ways to cut the rate of cesarean sections by eliminating unnecessary ones).

Conclusion

I have presented comments from two of the best thinkers and practitioners of QI in health care, both of whom have committed the past 5 years of their professional lives to learning about and practicing a new way to continually improve.

In his answer to the first question, "What is the essence of QI?" it is apparent that Batalden sees QI as a fundamentally new system of knowledge that complements existing knowledge. Caldwell views it in more concrete terms as just a framework, albeit the most powerful one he has ever seen, for achieving his hospital's organizational objectives. When asked "What is QI work?" both experts tell us that QI is not just one part of what they do everyday, it is their daily work. Batalden tells how his continual improvement work is tied up with continual learning and devising sure ways to connect theory and practice. His job is to teach health care leaders. To paraphrase the utilitarian philosopher James Dewey, the goal is not to find ways to make theory simple but to make practice wise.

Caldwell's QI work is fully integrated into his daily work as head of a hospital. This involves strategic planning, supervising, measuring, empowering all employees, and searching for clinical care innovations to meet community needs.

On the third question, "What have you accomplished?" it is clear that both men have accomplished a great deal, but there is an enormous amount of further work that must be done. This is bad news for people who are looking for quick fixes. Health care systems are big and complicated. Making substantial improvements in large health care organizations with respect to outcomes, efficiency, access, costs, and satisfaction will take years not months. Ford Motor Company has been working on quality for nearly 10 years. Its executives think they are about 20 percent along the way of fully using a QI process, but Deming puts it at less than 10 percent.

Besides taking time, if health care providers are to learn to accelerate their ability to improve quality and value, they will need to cooperate with each other in new ways, and they will need reinforcement from business leaders, policymakers, regulators, and researchers.

As for the fourth question, "How could QI research be put to work?" it is clear that in theory quality research could be extremely valuable for improved quality, decreased costs, and greater overall value in health care. But to actually help health care providers, who are key beneficiaries of quality research, it must be grounded in a firm understanding of QI theory and practice and the system of care delivery as it actually exists, with its constraints and accelerators, its barriers and supports.

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Quality Improvement: A Patient's Perspective

Charles E. Silberman

Introduction

To quote Heather Palmer (in this volume), "Quality is defined as meeting the needs and expectations of customers." There are many customers, of course—some internal, some external—but the ultimate customer is the patient; if this enormous health care enterprise is about anything, it is about meeting the needs and expectations of patients.

My purpose for the conference and for this paper is to speak to you as a patient—a far more frequent patient than I might have wished—and from that vantage point to tell you how we are doing and what we need to do.

We are doing poorly. The health care system fails the Palmer test: it does not meet the needs and expectations of patients; it does not create satisfied customers, which Peter Drucker calls the only valid business purpose (Moloney and Paul, 1991). The health care system fails to do so because under the prevailing system of doctor-patient relations, patient preferences play only a minor role; the demand for medical care is largely physician-induced. True, patients initiate most medical encounters, but they have little to say about what happens thereafter; doctors, not patients, decide whether patients will be hospitalized and whether they will undergo surgery, chemotherapy, or some other treatment or procedure. Physicians make these decisions with the best of intentions; they genuinely seek to meet the needs of their patients. But physicians—not patients—define those needs. Physicians usually do so, moreover, without asking patients what they want or think they need and without otherwise taking patients' preferences and values into account.

Physicians make these decisions unilaterally, not because they crave power but because, until recently, everybody took it for granted that "doctor knows best." That assumption, in turn, rested on four other assumptions, namely:

1. Physicians know the scientifically correct way to practice medicine.
2. They know the values and preferences of their patients.
3. Physicians are disinterested and objective scientists without preferences or biases of their own.
4. They therefore routinely choose for their patients what those patients would choose for themselves if they had the same knowledge.

None of these assumptions can withstand scrutiny. As Jack Wennberg (1984, 1987, 1988; Wennberg, Freeman, and Culp, 1987), Robert Brook (1991; Brook and McGlynn, 1991; Winslow, Solomon, Chassin, and others, 1988), David Eddy (1982, 1984, 1990a, 1990b; Eddy and Billings, 1988), and others have shown, physicians frequently do not know the scientifically correct way to practice medicine—not because of personal ignorance or indifference, but because nobody knows; medical science has enjoyed spectacular success in developing new diagnostic tests and treatments but has failed to evaluate the usefulness of those tests and the outcomes of those treatments. That, after all, is why the Agency for Health Care Policy and Research was brought into being. Like other human beings, moreover, physicians have biases and preferences of their own; they usually do not know, and indeed, often misjudge their patients' values and preferences.

These misjudgments are rooted in an enormous gulf between the way physicians think about disease and the way physicians experience it—a gulf physicians often discover when they become seriously ill themselves. "I practiced medicine for 50 years before I became a patient," Edward E. Rosenbaum, M.D., (1988) former chief of rheumatology at Oregon Health Sciences University, wrote in the book on which the film, The Doctor, was based. "It wasn't until then that I learned that the physician and patient are not on the same track. The view is entirely different when you are standing at the side of the bed from when you are lying in it."

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Perceptions of Illness and Disease

To the seriously ill patient, disease is an assault on identity and sense of self, an assault involving disorientation and loss of meaning, erosion of autonomy and control, fear, and dependency. Sickness also is a transforming experience. The transformation is most evident when sickness is chronic or progressive or leaves us with a permanent disability. But even if we "recover," we do not return to our pre-sickness state; we must adjust to a new way of seeing and relating to the world. To the patient, disease always is an existential process.

To the physician, on the other hand, disease is a pathophysiological process—one that is abstracted from the patient and his or her suffering. To a neurologist, for example, multiple sclerosis (MS) is a "slowly progressive central nervous system disease characterized by disseminated patches of demyelination in the brain and spinal cord, resulting in multiple and varied neurologic symptoms and signs, usually with remissions and exacerbations."

That is not how MS patients experience the disease. "What I experience every day is not the demyelination in the white matter of the nervous system," philosopher Kay Toombs (1992; see also Toombs, 1989) explains, but the "ongoing and seemingly relentless diminishment of physical abilities which is gradually but surely eroding my independence. For me, multiple sclerosis is the constant effort to overcome my body's resistance so that I can carry out the most mundane activities; it is the frustration of not being able to do the simplest of things. It is the anguished uncertainty of a perilous future."

I know what Dr. Toombs means. For me, a brain stem infarct—in laymen's terms, a stroke—was not "an intra- or extracranial interruption in arterial blood flow," as the *Merck Manual* (Berkow and Fletcher, 1987) describes it. It was the infantilizing inability to stand without collapsing to my left and the unimaginable terror that what already had happened to my hospital roommates would soon happen to me—that I would lose the ability to speak, think, write, or feed myself.

For patients, disease never is just a pathophysiologic process. "What happens when my body breaks down happens not just to that body but also to my life, which is lived in that body," explains Arthur Frank (1991), a medical sociologist who had a massive coronary followed by testicular cancer. "When the body breaks down, so does the life." Fixing the body "doesn't always put the life back together again," Frank adds, because serious illness "leaves no aspect of life untouched... your relationships, your work, your sense of who you are and who you might become, your sense of what life is and ought to be—these all change, and the change is terrifying."

Terrifying, as I can attest, because sickness plunges us into an abyss of meaninglessness; we know what our symptoms are but not what they mean. Sickness also is disorienting, for it shatters the web of assumptions on which our lives are based. We take it for granted, for example, that our arms, legs, fingers, feet, and other organs will respond to our usually unconscious commands. It is only when that does not happen—when we cannot stand without falling, as happened to me after my stroke, or when bringing a cup of coffee to our lips without spilling it requires all the concentration we can muster—that we discover the degree to which our sense of self had depended on those assumptions and how disoriented we become when our body turns into an enemy rather than an ally.

No wonder patients and doctors have such difficulty communicating with one another. "In discussing my illness with physicians," Kay Toombs (1987) reports, "it has often seemed to me that we have been talking at cross-purposes, discussing different things, never quite reaching one another." For the most part, Dr. Toombs adds, "this inability to communicate does not result from inattentiveness or insensitivity but from a fundamental disagreement about the nature of illness. Rather than representing a shared reality between us, illness represents two quite different realities, the meaning of one being significantly... different from the meaning of the other."

Improving the Quality of Health Care

We cannot improve the quality of medical care unless both realities are incorporated into clinical practice. Because doctors and patients understand disease so differently, they have radically different expectations of medical care and, therefore, radically different ways of assessing its quality. The assumption that disease is physiological leads doctors to set physiological goals and to measure the quality of care through "intermediate outcomes"—changes in physiological measures such as blood pressure, blood sugar levels, tumor size, or patency of blood vessels.

These are important outcomes, but they are incomplete, at best, and often tell the doctor little about how patients feel and function, the outcomes that interest patients most. In a host of chronic illnesses—conditions such as ulcers, angina, arrhythmia, diabetes, spinal stenosis and disk herniation, and benign enlargement of the prostate, among others—there is remarkably little correlation between the severity of the organic disorder and the amount of pain or disability patients experience; the same pathophysiology is associated with widely different symptoms in different patients. By concentrating on physiological measures, a rheumatologist observes, physicians "may all too easily spend years writing 'doing well' in the notes of a patient who has become progressively more crippled before their eyes" (Deyo, 1991; see also Smith, 1983).

That is not how patients define "doing well." By and large, patients judge the effectiveness of a drug or procedure by its impact on their lives. They want to know whether the treatment will relieve pain or alleviate anxiety; whether it will preserve or restore their ability to see, hear, walk, climb stairs, or dress and feed themselves, and whether it will change their appearance, sexuality, or mood.

In short, patients judge the quality of care by its impact on the quality of their lives—an outcome physicians and hospital administrators rarely measure. Clinicians collect information about the functioning of almost every bodily organ but not about the functioning of patients as a whole. "We appraise the palliative treatment of patients with cancer by measuring... tumor size and other paraclinical indexes," Alvan R. Feinstein (1983) points out. "We do not regularly measure whether the patient is comfortable or miserable, functional or bedridden, vegetating or vibrant. We compare medical and surgical treatment for coronary heart disease by measuring... patency of vessels, changes in electrocardiograms, and treadmill exercise tests. We do not regularly perform scientifically credible measurements of whether the angina pectoris is still severe, whether the patient was truly made able to return to work, and whether the quality of life has otherwise improved for the patient and his family."

These failures are due not to insensitivity or lack of concern but to the prevailing mind-set about the kind of information physicians should seek and study. By and large, physicians are taught that what cannot be readily quantified is unimportant; information about what patients think and how they feel or function has been considered "soft" or "subjective" and therefore less worthy of scientific attention than "hard" or "objective" data, such as the images, numbers, and tracings produced by diagnostic testing equipment. By making this invidious distinction, Feinstein (1987) notes, physicians ignore "all the distinctively human reactions—love, hate, joy, sorrow, distress, gratification—that differentiate people from animals or molecules."

Ignoring or slighting the human dimensions of medical care is scientifically untenable; it grows out of an obsolete view of the nature of science. It also is unnecessary. Physicians and hospital administrators now have at their disposal a number of easily used, as well as valid and reliable, instruments for assessing patients' symptoms, functional status, and sense of well being. As Sheldon Greenfield (in this volume) points out, some of these measures are actually "harder"—that is, more valid and reliable —than many of the physiologic measures in common use. The availability of these measures makes it scientifically as well as ethically intolerable for providers to fail to be as concerned with their patients' functional status and well-being as they are with their patients' physiologic status.

Physicians and hospital administrators no longer have a choice. Consumerism is rampant; *Business Week* (King customer, 1990) has called the 1990s "the decade of the customer." As Thomas Moloney and Barbara Paul (1991) point out, members of the so-called "baby boom" generation want far more information than their elders about the services they buy, including medical care. Indeed, the Picker-Commonwealth survey that Paul Cleary and colleagues (1991) describe found that Americans are eager to use survey data to help them decide where to seek medical and hospital care.

Thus, periodic surveys of patient attitudes and experiences must be incorporated into any quality improvement effort; and assessments of patients' functional status and well-being must become a routine part of medical and hospital care. But surveys and assessments are not enough. Patients are demanding more than information; they want to play an active role in decisions about their own care.

That demand must be met; collaboration between patient and physician is a scientific, ethical, and economic imperative. An ethical imperative because there is more than one medically appropriate treatment for almost every illness or condition, and because each treatment poses a different set of

risks and benefits whose probabilities often are not known. Because patients differ widely in the degree to which they are bothered by a particular symptom, moreover, they attach widely different values to its relief. Patients also differ widely in their willingness to assume the risks of treatment. Much of the time, therefore, there is no medically "right" or "wrong" decision; what is "appropriate" for one patient may be wholly inappropriate for another. Choice of treatment must involve collaboration between doctors and patients.

Collaboration between doctor and patient should not be limited to the choice of treatment; it must start when the patient first seeks medical help and continue throughout the clinical encounter. If quality is defined as meeting the needs of the customer, the physician must find out what those needs are. Something has happened, after all, to make that patient seek medical help. Without knowing what that something is—what caused the patient to come and see the doctor (and patients are not always aware of the real reason themselves)—the physician may identify and treat the wrong problem.

The risk of treating the wrong problem is increased by the staccato, close-ended style of questioning most physicians favor, a style that makes it hard for patients to reveal what is on their minds. In analyzing doctor-patient interactions, Beckman and Frankel (1984) found that, on average, physicians interrupted patients 18 seconds after the patient began to speak; patients were able to complete their opening statements in only one visit in four. Time is not the problem; when patients were permitted to complete their statements, they took only 60 seconds longer.

Indeed, interrupting the patient may lengthen the visit rather than shorten it. Witness the familiar situation in which, just as the physician thinks the office visit is over, the patient asks, "Oh, by the way doctor, I have been having this heavy feeling in my chest. Do you think it might be important?" Most of the time patients are not being perverse; rather, they have not been able to get the question out when the doctor takes their history, or the doctor may not put them at sufficient ease to enable them to ask an embarrassing question or one they are afraid to ask because its answer may be frightening.

The only way patients can tell physicians why they are seeking medical help is through genuine dialog; and genuine dialog cannot occur unless physicians establish comfortable relationships with patients. "To be humane and empathic is not merely a prescription for compassion," George Engel (1988) explains. "It is a prerequisite for scientific work in the clinical realm."

Paying "proper attention to the full needs and feelings of patients" (the formulation is that of Oliver Sacks, 1987) is not an impossible task. Thomas Delbanco (1992) of Beth Israel Hospital describes one way of doing that. In their encounters with patients, Delbanco suggests, doctors should conduct a "patient review" comparable to the organ-specific review of physiologic symptoms that is part of every physician's routine. Delbanco describes seven dimensions of care that need to be reviewed and suggests questions the physician might ask in each dimension. "Incorporating the patient's review into my interactions with patients encourages me to address the nontechnical aspects of care in a systematic way," he writes.

Conclusion

To sum up, quality improvement involves more than measurement; it requires a broadening of the goals of clinical practice and a transformation of the patient-doctor relationship. The best physicians have always understood this. As Francis Weld Peabody told his Harvard Medical School students 65 years ago, "One of the essential qualities of the clinician is interest in humanity, for the secret of the care of the patient is in caring for the patient." It may not have been entirely coincidental that when he delivered his classic lecture on "The Care of the Patient," Dr. Peabody was himself a patient, under treatment for the cancer that killed him later that year.

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Closing Quality Improvement/Quality Assurance Information Gaps: AHCPR's Role

John Ball, M.D., J.D.

Introduction

For me this was a learning conference, and it will be difficult for me to say something new. Instead, I will try to summarize and briefly discuss the themes that came out during the presentations.

First, you should know that I am speaking from the perspective of a physician-clinician. David Sundwall and I planned our remarks to be somewhat complementary. David will discuss the physician in the hospital and management role, and I will focus on the physician in a clinical role.

I also bring a personal history to my remarks. About 20 years ago, I was chief of the medical audit branch of the division of peer review in the Bureau of Quality of Assurance. My responsibility was to design and implement the policy that the professional standards review organizations would use in quality assurance (QA). I also had the ancillary task of helping to determine which medical procedures Medicare would cover. It is interesting to see where things are now. I worked with James Roberts, who is with the Joint Commission on Accreditation of Healthcare Organizations; Dale Schumacher, president of the Commission on Professional and Hospital Activities; William Jessee, who is working with QA at Humana; Mark Chassin, who is the commissioner designate for health for the State of New York; and finally, Helen Smits, who was director of the health standards and quality bureau, Health Care Financing Administration. We were a group of people who believed QA had a lofty purpose, that we were part of something worthwhile and exciting, and that government could be activist and have a positive role with health care in the country.

I have a recent history in this area as well, although it is informed by that past. First, with the American College of Physicians, I have been involved in technology assessment and the production of clinical guidelines—standards for health care—under our Clinical Efficacy Assessment Project. That role has taught me that professional societies have a broader role than merely looking after the economic and political power of our membership; we must work in collaboration with the people who are developing health policy.

Second, I have been involved more recently in the Robert Wood Johnson Foundation Hospital Quality Improvement Program where we are looking at how hospitals can work cooperatively, both with each other and with the medical staffs. One of the things I have learned from reviewing over 100 applications for the project is that the state of QA in this country is not very good. There is no cooperation between hospital administration and medical staff, or among hospitals, and there is certainly no sharing of the kind of data that consumers, customers, and others need to make appropriate choices in health care.

Third, I have been a judge for the Health Care Forum/Witt Quality Award, the commitment to quality award for hospitals and institutions, and I have reviewed a number of applications from people who think they qualify for the award. Again, the disappointment is that, even in the best of hospitals, medical staffs are operating in QA separately from patient care QA and certainly apart from the kind of QA that the administrative and management side of the hospital wants to implement. One of our most important challengers is to bring these groups together for patient QA rather than medical QA alone.

Finally, I have been on the board of a hospital, but like all other hospitals in this country, QA was looked at by the medical staff as something peripheral, not central, to their activities; we need to change that. These experiences have led me to certain biases that will come out in this discussion.

Back in the fall of 1991, when the Agency for Health Care Policy and Research (AHCPR)

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organized this conference, they asked me to do a wrap-up on the last day of the meeting. More recently, they asked me to present my views on the domains of the public and private sectors in this area and for my thoughts about how AHCPR and other Federal agencies can complement efforts by the medical profession and other private sector groups to improve the science and practice of QA. They also asked for my perspective on the ways in which medical effectiveness and outcomes research, as well as general health services research, can be coordinated with quality improvement (QI) more effectively. Finally, they asked for my views on related policy concerns including the potential role of AHCPR in health care reform initiatives. I will try, given my biases and perspectives, to summarize the themes that emerged during this conference and to identify some of the thematic areas that I would like to see the AHCPR develop.

Conference Summary

Helen Smits (in this volume) set the theme: "There is more to health care policy than cost containment" and suggested that we all look at the larger policy context and the real goals of health care policy. She listed them as access, cost, hassle, and manpower. Then she gave us the litmus test: Democrats mention access first, Republicans mention cost first. I throw my vote in on the access side. She also said, "be aware and beware of the barriers to moving to continuous quality improvement and quality assurance," two of which I mention again: rigid professional disciplines and the outsider status of the medical staff. I think we need to bring discussion of these items back into QA and QI within the hospital.

Just before I began my presentation, someone in the audience handed me a note that said, "There really are only two questions: (1) Does it work? and (2) If so, why?"

Sheldon Greenfield (in this volume), in talking about the medical outcome studies, raised a point we need to listen to more often: "A health service is not a health service," it's part of a package that involves both caregivers and the person receiving care. One needs to take into account not merely the service but also the caregiver and the person receiving care.

Heather Palmer (in this volume) gave a fascinating taxonomy of where we have gone, from the professional model to the bureaucratic model to the industrial model. She did not conclude like many other economists by saying that all you need to do is change how you pay and how much, and the health care problem would be solved. Instead, she said, "What we need to do is to combine the best of care with the best of science and management." I think that is our real goal here—a transformation from the adversarial system we now have to one based more on concepts of trust, collaboration, cooperation, and the complementary nature of the systems of care.

Finally, there were two questions from the audience that had meaning for me: What are we really about here? What is this alphabet of TQM, CQI, QI, and QA? That should remind us of what Paul Lembke and Beverly Paine did in the 1940s. They said, "Before you begin the medical audit for disease make sure in fact the patient had the disease you are auditing for." The second question that came from the audience was, "Does all this outcome research, effectiveness research, guidelines, and so forth make a difference?"

How do I combine my bias and perspective with what I think I heard? I believe it merges into one basic theme: the patient-physician interaction is critical. The principal focus of all that AHCPR does should be to improve continuously the quality of that interaction. I do not mean to ignore other perspectives, but I intend to use the patient-physician interaction as the model from which the others can be extrapolated.

Continuous quality improvement (CQI) begins with a customer and what the customer wants and needs. I believe that the principal customer of CQI or the health system is not the payer, it is the patient. It is not even the provider, who in my view is secondary, and it certainly is not government and other purchasers. It is first and foremost the patient.

CQI also says we have to empower the participants in the system, and that means we need to empower patients first. Physicians and other professionals also need to be empowered—not in the political and economic way, but to improve.

Finally, CQI says we have to provide standards of measurement and feedback via monitoring. AHCPR is in a good position to be a catalyst for CQI, and it should take the risk to do so. The list of research questions presented at the conference looks like a list Congress might ask at a hearing. I believe we need to return to very basic principles and take very basic kinds of risk. How do we do that? Responding to the charge of Helen Smits,

I would argue the goals of health policy are very simple: appropriate health outcomes from appropriate health services for an appropriate price in the context of societal agreement on how much we are willing to spend.

AHCPR's Role

I think the first thing AHCPR needs to do is make a clear commitment to its mission—in my view to become the primary quality information resource—by developing information on health outcomes and the effectiveness of health services. Second, to improve health outcomes, AHCPR should develop, with input from caregivers and patients, guidelines of clinical appropriateness and the least intrusive monitoring systems and feedback mechanisms for continually improving health services. Third, I would argue that AHCPR has a basic mission to catalyze societal discussion about value by including all segments of society: physicians and all other health caregivers, patients, payers, and all others. I think AHCPR should focus on the quality of the process and not worry so much about QA mechanisms. In QI, the participants, patients, and physicians have the incentive to be the primary actors, while in QA the participants are secondary. In QI they become a collaborative team. I suggest focusing on the service end of QI, not the oversight end of QA. How could that be done? I think there are four basic activities AHCPR might accomplish:

1. Work on appropriate outcomes.
2. Work on appropriate services.
3. Work on catalyzing discussions of societal value.
4. Act to make information manageable.

Outcomes. First, AHCPR should begin work on appropriate outcomes. In addition to continuing its research on clinical effectiveness and outcomes, AHCPR should listen to the customers, that is, the patients. Patients' values differ from those of researchers, physicians, or hospital administrators. If you doubt that, consider what the Dartmouth videos are beginning to teach us. Remember what the Yankelovich survey from a year ago said about the difference between the ways the lay public and the experts look at health care problems. Physicians who doubt that there are differences should think about what they value in the physician-patient encounter compared with what they value as physicians.

Patients have different values than providers, and we need to listen to them as customers. AHCPR needs to work with the public and with professional groups to do research in four particular areas related to appropriate outcomes: first, research on patient values (what patient and physician characteristics make a difference in care); second, why certain services lead to certain outcomes; third, the linkage between outcomes and process; and fourth, ways in which the appropriate and least intrusive systems possible can monitor what occurs.

Appropriate services. Let us accept the fact that physicians are good people and intend to do the best for their patients. Rather than try to identify the "bad apples" or the "rotten eggs," we should assume that most people want to do well and help them do so.

What must physicians and patients do to provide the best services in the clinical situation? I would argue they need four things: valid information, a credible source of information, an incentive to use the information, and a safe environment in which to use the information.

Simply because we do not have perfect information everywhere does not mean we should not move forward. Valid information is simply the best information developed using the best existing data and the best expert opinion. We can begin developing guidelines for appropriate clinical care based on that information rather than waiting for perfect answers.

What is a credible source for information? The payers are not credible sources of clinical guidelines, nor are most professional societies, but together we ought to be able to come up with credible information. Instead of having self-interest rule, we need real collaboration. I see AHCPR as the perfect institution to develop that collaboration, and I applaud what it has already done in this area.

In my opinion, AHCPR does not have a direct role in establishing particular financial incentives to use information. But I do believe AHCPR might appropriately educate. Research is like the tree falling in the forest; without educating the people who will use it, the information is useless.

Physicians need a safe environment in which to use information. Physicians and others will not participate in technology assessment, guidelines development, QA, or QI if they perceive that the information will be used to punish them. We need to create environments where the emphasis is on improving quality of care rather than punishing and

sanctioning people. The role of AHCPR, in my view, should be to develop valid information, work cooperatively as a credible source, and stimulate the development of safe environments.

Foster discussion of societal values. AHCPR should involve broad segments of society in its initiatives. Outcomes and effectiveness research and evaluation should include not just researchers or providers or payers, but also the customers/patients. AHCPR needs to involve patients in guidelines development as well. For example, what outcomes are valued? How can they be taken into account? Finally, AHCPR should involve customers and/or patients in medically effective payment policy.

In reality, all existing and proposed benefit packages in health care systems reform are for the benefit of the payer; they list things that will not be reimbursed. What if we were to design a benefit system to benefit the patient—for example, the patient who might need more than 100 hospital days? Why should we cut it off at 100 days? A patient might need more than 10 visits to the psychologist—why do we cut it off at that? How could we design a benefit package from the perspective of the patient? AHCPR could be active both in the process and the policy of bringing that about, involving patients in designing a medically effective benefit package.

In working to catalyze discussions of societal values, AHCPR needs to stimulate the educated customer and the patient. In one of the work groups on patients, Lisa Sullivan talked about the work she and Sheldon Greenfield did in the medical outcomes study whereby patients were empowered, not so much with clinical information—patients can never know all the clinical information that physicians know—but they were empowered so they could ask the right questions and have the tools to negotiate. AHCPR could fill an important role in helping patients become partners in care by teaching them how to talk to physicians and how to become partners in decisions about their care.

At the American College of Physicians we are publishing a health letter that contains information patients need, but we do not send it to patients; we send it to physicians to teach them how to teach their patients. AHCPR could be very effective in enhancing the participation and interaction between physicians and patients and by stimulating the educated customer/patient.

Also, AHCPR should consider education of the media. Now, patients are educated by the media in scary ways, in *National Enquirer* "miracle cure" style, or through the reporting of so much information that they are overwhelmed. Clearly, there is a role for government here. Since I do not see it happening elsewhere, perhaps AHCPR could help to educate the media on how to educate the public.

I would argue that AHCPR should work with payers—not in the sense of giving them information about which services they are paying for or helping them make those decisions—but by helping them to translate clinical guidelines appropriately into payment guidelines and from there into review criteria. If payers take the clinical guidelines without the ability to translate them, there could be a disjuncture between clinical guidelines and payment guidelines. Clearly this can be done with the Health Care Financing Administration, and it also might be accomplished with other payers within the system.

Making information more manageable. Each year 4 million biomedical articles are published in 29,000 journals worldwide. That is too much information. AHCPR could have a role in collecting, analyzing, distilling, and disseminating usable and relevant information to practitioners. In the private sector, the American College of Physicians publishes a periodical called *ACP Journal Club* six times a year. This is a survey of 40 biomedical journals, the ones we think are the best. Six times a year we pick the 32 most important articles from those journals and publish a structured abstract of each article with a one-page critique. Granted it is the *USA Today* of medical literature, but we have received kudos for it from our members, who say that it has enabled them to sense that they can in fact get their arms around internal medicine. AHCPR has a role in collecting, analyzing, distilling, and disseminating information. That could be a practical benefit in the physician/patient interaction.

AHCPR has a great practical role in educating management, particularly in quality management, at least at the medical school level (by helping the educators educate in the appropriate use of technology) and certainly with continuing medical education. As pointed out during this conference, physicians do not know much about quality management, and it is the rare physician who is really trying to do it. Frankly, it is the best way for physicians to go.

It is interesting to go to a hospital mortality or morbidity conference and hear the discussion. The

purpose of the discussion is to find out whether God was at fault ("God's will"), or the physician was the culprit. That does not teach anything because the great incentive when those are the only two options is to blame God. What we should be doing is looking at events and trying to find out how can we learn from them and make improvements. No one teaches that well. AHCPR has an important role in making the information manageable, particularly information about quality management and CQI.

Role of Professional Societies

What is the professional society's role in interacting with AHCPR? It comes down to one word: leadership. Professional societies finally need to take the risk for societal gain in two areas: one, to set standards cooperatively with AHCPR; and two, to cooperate not only with AHCPR but also with patients, payers, labor, consumers, and industry to try to reform the health care system. This will not be accomplished by all of us taking our separate positions and fighting about them. We have to come together collaboratively, and unless professional societies take the lead, I do not believe we are going to get anywhere. Unless we do this, we will not be sending the right message to practicing physicians.

Conclusion

In summary, AHCPR will have a central role in any reformed health care system of the future because there will always be greater demands for health services than resources available to meet them. Societal choices must therefore be based on attempting to improve health care outcomes by continually improving health services. By focusing on the patient-physician interface and viewing the informed and empowered patient as the customer, we have the best chance of reaching the goal of improved health care.

In my view, QA needs to be transformed into QI. If it is, then a partnership can and should develop—not an assessment for punitive sanction, but a cooperative evaluation to improve care. This is different in concept, difficult to achieve, but critical to begin.

Closing Quality Improvement/Quality Assurance Information Gaps: Public and Private Sector Roles

David N. Sundwall, M.D.

Introduction

I compliment J. Jarrett Clinton and the Agency for Health Care Policy and Research for sponsoring this conference. I see AHCPR as a complementary force to the Health Care Financing Administration (HCFA) in assisting those of us working in the private sector. I welcomed this assignment because it gave me a chance to focus on the impressions I have had for some time about what is right and wrong in hospital quality improvement (QI) efforts, and like John Ball, I am going to talk from the point of view of a physician, but one who for 3-1/2 years has been involved with the not-for-profit hospital community. I apologize to others who have a different perspective, for example, home care, or nursing care, or other areas that are equally important.

American Health Care Systems (AmHS)

I will take a moment to describe my organization and why we care about quality in health care. American Health Care Systems (AmHS) was established about a decade ago as an alliance of multiple hospital systems. We have 40 systems, representing 1,100 facilities in 47 States. Their annual revenues total $22.5 billion, and they constitute about one-fifth of the Nation's not-for-profit hospital beds. These 40 hospital systems all have a not-for-profit mission, and most of them have a religious heritage. Their mission is to serve their communities, and the alliance exists to make them more efficient and economical.

The credo of AmHS is to assist our member hospitals in providing the highest quality of health care at the lowest possible cost. We do this through a broad range of services, and this includes the promotion of quality. I say promotion of quality, because as an alliance, we can cajole, persuade, and encourage our member hospitals that the best care possible is good for their bottom line and competitiveness, as well as important to their missions, but we do not have any leverage over them. The following are some of the things AmHS does to promote high quality care.

Education. In June 1989 we began publishing *The Quality Agenda,* an annually updated monograph that provides an overview of who is doing what with regard to health care quality issues. It is hardly a comprehensive list or directory, but it provides a broad overview of quality-related activities being undertaken by the Federal and State governments, business coalitions, the Institute of Medicine, academic groups, and other interested parties. We did this because it helps sort out multiple activities and helps our hospitals anticipate new developments. We also make clear that quality should be understood as documentation of value, accountability, and public disclosure.

Another annual activity is our sponsorship of a QI education conference. We focus on quality-related national health policy and trends, and we provide an opportunity to highlight AmHS quality activities that have been successful. We schedule national leaders to tell us of their particular activities—for example, Dr. Clinton spoke a few years ago, and last year we heard from Nancy Gary, the physician advisor to HCFA. At the request of the Board of AmHS we also make our conferences clinically oriented. They have been fairly successful in having management embrace the concepts of continuous quality improvement, but they have been less successful with engaging medical and nursing staffs in such efforts. Periodically we also publish other educational materials that are devoted to quality issues.

Research. We also conduct research at the AmHS Institute. For example, we did a recent study in collaboration with the Johns Hopkins Center for Hospital Finance and Management on excess hospital capacity, in which we concluded that there are

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approximately 200,000 excess acute care beds in the United States. We did another analysis comparing not-for-profit hospital tax benefits with their contributions to their respective communities. This raises interesting policy issues, because while the majority of our systems collectively provided more community service than they gained from the government tax exemption, some systems do not. Consequently, we will be repeating the survey, with a goal of establishing a standard of community service that all of our members should strive to achieve.

As part of our research effort, we have participated as a charter member of the Quality Measurement and Management Project (QMMP), run by the Hospital Research and Education Trust (HRET), a 4-year project scheduled for completion in the summer of 1992. Its intent is to demonstrate leadership among the hospital community by developing scientifically sound comparative hospital outcome studies based on available hospital data and promoting nationwide use of a simplified uniform method of hospital quality management. We published a series of monographs that are helpful and established a dialogue with several nonhealth entitles interested in hospital quality data, such as businesses, the academic community, employers, and regulators. Some attending this conference have served on our external advisory group or as technical advisors.

Discounted contracts. Because we are in the business of providing savings for our members, we seek favorable contracts for a variety of goods and services that are hospital quality related. In return for a significant discount, generally based on the number of our hospitals participating, we provide introduction and opportunities for vendors to educate about the potential merits of their products which are designed to improve the quality of hospital care.

Hospital Quality: Where Are We in the Revolution?

Now I will share with you some personal impressions, as John Ball did from his perspective. I have been working for over 3 years in the not-for-profit hospital community, and it has been a fascinating education for me. I have learned to walk in another person's moccasins because I came to my current position with some of the same prejudices that John described regarding the conflicts between the hospital and the doctor. The interface between hospitals and doctors often is tense and troublesome, reflecting what are considered competing and conflicting interests.

Positive developments. The following are some of my positive impressions. One is that multiple efforts from a variety of sources (many of them very creative and innovative), both internal and external to hospitals, are directly affecting the quality of care provided in hospitals and collectively are making a difference. Please do not ask me for my measurement instrument; I come to this conclusion from a growing list of anecdotal reports from a number of our member hospitals that cite improving efficiency, decreasing cost, better morale for their providers, and more patient satisfaction. However, valid measurement tools are wanting, and many of these results are self-reported.

Second, through the wonders of computers, large data bases have in recent years given us the wherewithal to make clinical decisions based not just on our colleagues or the CME course we went to last year but on thousands of patient encounters. This is a real plus, and I think there is a lot of promise that such data systems can provide valuable tools for much improved quality of patient care.

My third impression is that there has been more attention on health service research, which is long overdue. I now have a decade of experience at the Federal level in health policy, and while I enjoyed the oversight hearings on the National Institutes of Health, which focused on biomedical research, I was increasingly pained by the relative lack of support for health services research. Fortunately, more attention is being paid to such research because of the recent focus on outcomes and practice variation. It is appropriate and most welcome.

A fourth impression is what I call the medicalization of QI. I do not want to limit this to physicians, because increasing numbers of physicians and nurses are becoming involved in QI at the hospital level, as well as at the corporate level of hospital systems. This is an encouraging development. It holds the promise of identifying, in a way we have not previously done, genuine common interests among the hospital managers and doctors, enabling the bonding that is frequently talked about and diminishing the differences and barriers that get in the way. When clinicians are given quality-related information, they generally welcome a chance to wrestle with data and figure out how to make better choices and clinical improvements.

The fifth observation is the constructive new agenda of the Joint Commission on Accreditation of Healthcare Organizations. I think it is an important step forward. They have fostered a lot of participation among physicians in the development of their new quality indicators. I realize we can quibble about the pace at which this is progressing, but at the same time it is movement in the right direction.

Possible problems. The following are some negative impressions of the quality movement, concerns that were reinforced at this conference. I will start with what I call the commercialization of QI. As we have an opportunity to listen to the vendors of goods and services and consultants, I am amazed at how many firms are getting into the business of assisting our hospitals with QI and have developed products or services costing hundreds of thousands of dollars. I am concerned because there has been little validation and testing of many of these products and services. We advise our members to make sure that the quality-related consultation, goods, or services are appropriate for their institution; they practice due diligence before making a decision to purchase; and they have the necessary trained personnel to ensure the desired outcome.

Second, I am convinced we are at the beginning of a "quality race," akin to the technology race, where hospitals, fearing they are losing their market or not being as aggressive as the hospital down the street, are embracing untried and unproven products in an attempt to keep pace. This quality race can impede success because, in their impatience to get on with it, they have neither laid the necessary groundwork nor invested in sufficient training or personnel. For example, although I love the Nike approach of "just do it," when it comes to QI, impatience and inadequate emphasis on infrastructure, resources, and personnel can compound problems.

My third negative impression is the problem caused by the demands for data placed on hospitals. Later, I will discuss what we are trying to do to correct that, but I can assure you it is a significant and costly burden. A variety of organizations want to assess how well our hospitals are doing, and in the process they are surveying us to death. A member of the audience at our annual conference in 1991 vented her anger at the HCFA representative after her presentation. She gave a litany of seven surveys she had been asked to complete in the previous 6 weeks. Such quality-related surveys are often cumbersome, time consuming, and collectively a tremendous burden on our hospitals.

The fourth problem I have observed is the prevalence of data illiteracy. Many hospital personnel, expected to "get with it" on quality initiatives, are simply not prepared to understand or use many of the tools they are expected to use. Many QI hospital folks are intimidated and turned off by complicated data management systems and hospital comparative reports, and I think more "user-friendly" systems and technical assistance are needed.

Fifth, while data are not the same as information, some purchasers of health care unfortunately do not understand the difference. Major decisions about purchasing and contracting are being made based simply on data, not meaningful information.

The last issue I will cite is one others have mentioned, and that is extraordinarily poor coordination. As we undertake multiple QI initiatives, we are in danger of contributing to the cost and inefficiency of hospital management, if all interested parties can't come together and agree on an appropriate data management and measurement system. We very much need partnerships of the public and private sector if we are to become more effective and not contribute to the problems.

External Data Demands

For the QMMP, I chaired a subcommittee on external data demands. We have produced a monograph that captures some of our thinking about the multiple requests for hospital quality data from many diverse organizations. It describes our concern about the expense, confusion, and misunderstanding and the invalid assumption that might be made from the data we provide. In short, we desire to bring order out of chaos and to promote consensus among all parties: governments, purchasers, payers, researchers, and providers. What we do not want to do, by any means, is stifle or discourage requests for quality-related hospital data, and we do not want to give external organizations just the hospital data they need or limit what we are going to give. We do not think it feasible to develop a definitive data system that could be applied to all settings, but we do want to do the following things:

- Reach out to those who are interested in establishing ongoing collaboration between all interested parties on hospital quality information.

- Develop consensus on uniform data management system (not the specific data elements).
- Establish a dialog between all interested parties to enable the revising and updating of this process over time. The process should be dynamic.
- Apply the system to hospital quality management as well as external reviewers to the extent that it is the same, and saves redundancy, and would be complementary.

To do these things, we documented the scope of external demands in an HRET publication titled "An Inventory of External Hospital Data Demands." This report demonstrates our burden in trying to accommodate the external demands from many people and entities interested in how well we are doing. Second, we invited a broad group of technical advisors to meet with the QMMP task force in Chicago to advise us on what information they felt was essential to make meaningful judgments. We then developed some guiding principles and a conceptual framework.

I have heard others refer to the enormous amount of available data of questionable usefulness. Dr. John Williamson of the Veterans Administration Hospital in Salt Lake City has done some interesting research on this topic. He believes that from the universe of data which are theoretically useful in measuring whether something is good or bad, only certain elements will prove really useful as they are subjected to a series of relevance filters and applied to testing. Such data elements must be used—that is, they must go through a maturity filter over time—and they must be subjected to scientific rigor. A limited amount of data is left that is replicable, valid, and useful across the board.

We are in a primitive state with data management; I am afraid that many of us are still floating in a sea of data, much of which is not likely to be very helpful. An important part of the quality research agenda will be to help validate some of these data elements. Our QMMP committee concluded that there are four categories of hospital quality data that are worth collecting, and if we can get others to think according to these categories, we can develop a simplified and more useful system of quality data management and reporting. The categories are: appropriate treatment indications for major process factors; medical outcomes, which include functional and patient satisfaction; price, charges and costs; and practitioners' satisfaction (we believe the morale of providers is an important indicator of the quality of care).

AmHS Quality Initiatives

AmHS will proceed with two quality-related research projects in the near future:

1. A feasibility study of AmHS maintaining a centralized QI data monitoring system for our member hospitals. We have selected the PRAGmatic System (developed by Corporate Cost Management in Rockville, Maryland) for testing, using a sophisticated analysis of data elements obtained from the Uniform Discharge Data Set, to give us four indicators (mortality, long length of stay, short length of stay, and complications) for 882 risk categories.
2. Clinical benchmarking for MedisGroup hospitals. We have several hospitals that are using MedisGroup software systems, some because they are required to (in the States of Iowa or Pennsylvania) and some because they have chosen on their own to purchase the MEDIQUAL products. We will assist our hospitals using MedisGroup data to define what we call clinical benchmarks (that is, best practices) that complement clinical practice guideline development but are hospital-specific.

Conclusion

This conference provided a welcome focus on health care quality-related research, and it was a real service for the hospital community. We all have a lot to do to improve our country's health care system.

I will close with a plea for balance in research investment in basic science, such as improving the science of data management and developing indicators, and investing in applied research. Please help us develop some user-friendly tools as soon as possible. From my perspective, we are in the midst of a revolution in health care quality—its measurement, monitoring, and management—but we are very early in this process that was catalyzed by the dawn of the computer age and have a long and arduous struggle ahead of us.

Reference

Hospital Quality Related Data: Recommendations for Appropriate Data Requests, Analysis, and Utilization (Catalog No. F-169504). Chicago: Hospital Research and Education Trust.

Workshop Recommendations

Workgroup I. Information Technologies and Quality Improvement/Quality Assurance

Norman W. Weissman, Ph.D., Topic Reporter

Workshop: Automated Data Resources

Facilitator: John Kelly, M.D., Ph.D.
Research Discussant: William Tierney, M.D.

Workshop: Medical Informatics and Quality Improvement/Quality Assurance

Facilitator: Norman W. Weissman, Ph.D.
Research Discussant: Mark Musen, Ph.D.

The work groups on information technologies saw the future of quality improvement (QI) and quality assurance (QA) as very closely tied to the future of information systems. They therefore placed a high priority on research, development, demonstrations, and evaluations of the impact of information systems on quality. Members felt that information systems will support decisionmaking by patients and allow incorporation of their values into the decisionmaking process. It is therefore important to learn what existing systems can do—whether at the review level or at the level of patient system supports—and what improvements in data analysis and aggregation can be made.

Finally, the group felt that diffusion was greatly affected by factors other than health care and encouraged social science research on factors leading to the adoption and use of information systems. Special attention was directed to issues of confidentiality and privacy.

Research needs were identified in seven areas involving use of automated data resources:

1. What are the effects of automated information systems on quality? Assertions are often made about the quality-enhancing abilities of electronic information handling systems, but such claims need evaluation and assessment by parties independent of the developers and marketers of such systems. This includes not only hospital information systems, but also smaller systems used by individuals.

2. How can patient-specific probabilities and utilities be incorporated into decision support systems? The patient cannot be left out of considerations of quality. Information systems in general, as well as high-technology decision support systems of the future, can provide a way to include patients' concerns in decisionmaking, but they must permit improvements in quality of care for specific patients.

3. How can data in existing information systems be used, and what elements should be added to improve quality? Discussion of research needs ranged from the reliability, transportability, and validity of currently collected information to the specification of additional elements for multiple applications.

4. What are the sociologic factors that influence the adoption of information systems technology? The ability to use information resources is very dependent on organizational and environmental variables. Sociologic research is needed on implementation processes in different settings with different applications.

5. What are the roles of technology, policy, legislation, and public opinion in solving the problems of privacy and confidentiality of electronic records? Privacy and confidentiality are major concerns with electronic data systems, especially with data collected longitudinally which require use of identifiers to link successive records. It was agreed that most data suitable for use for QI would need to be linked. To avoid inappropriate use of the data, it was recommended that technologic and legislative solutions and the utility of policies and public opinion in influencing the use of such data be investigated.

6. What methods are appropriate for analyzing longitudinal data sets? Most of the analytical tools that have been developed for health care research have been for experimental studies. It was recommended that methodological research be given a high priority, with attention to issues of sample selection, choice of variables, and modeling.

7. What are the most effective ways of disseminating the systems that improve quality and the information derived from these systems? Many discussants pointed to the lack of diffusion of information about existing successes, as well as failures, and urged research to improve dissemination to avoid unnecessary replication of mistakes.

Workgroup II: Methods and Measures for Quality Improvement/Quality Assurance

Marcia Orsolitis Stevic, R.N., Ph.D., Topic Reporter

Workshop: Quality Review Criteria

Facilitator: Carole Magoffin
Research Discussant:
Marcia Orsolits Stevic, R.N., Ph.D.

Workshop: Performance Standards

Facilitator: Margaret O'Kane
Research Discussant: Vahe Kazandjian, Ph.D.

Workshop: Improving the Science of Quality Improvement/Quality Assurance

Facilitator: Leon Wyszewianski, Ph.D.
Research Discussant: Haya R. Rubin, M.D., Ph.D.

The work group on quality review criteria demonstrated an appreciation of the role of scientific studies in the diverse arena of QI/QA. A number of themes became apparent in the discussions. There was concern about the variation in needs among health care sites that may be in different stages of development in their ability to measure quality or implement more sophisticated methods.

Issues involved in dealing with different populations were another concern, including the needs of diverse ethnic and cultural groups and different age groups. Both short- and long-term needs for QI review criteria were examined. Concern was expressed about some tools that may have been too quickly marketed and adopted and may now need to be re-examined for reliability, validity, and ability to give information across sites. The relationship between guidelines and criteria was also discussed.

Research needs were identified in three areas of quality review criteria:

1. What are the best methods for developing, implementing, and evaluating review criteria? What are the links between process and outcome? What are the best methods of feedback to change practice, and what elements of practice are most amenable to change? Discussants considered the link between process and outcome to be a key issue.

2. What are the best ways to design and measure guidelines and criteria across sites of care, taking into account identification of the locus of responsibility for decisions? It is sometimes difficult to identify who is responsible for what portion of care. As emphasis on a continuum of care increases, this issue will become more complex and challenging. The issue is not only who has responsibility for what portion of care, but also who has input to shape the evaluation criteria and who receives information about it.

3. How do national and local criteria compare? How do criteria developed from the generalist perspective compare with those developed from the specialist perspective in terms of acceptability and usefulness? It was appreciated that acceptability and usefulness are intertwined; people who decide that some things are unacceptable are not likely to regard them as useful, although in other arenas they might be.

Discussants in the workshop on quality standards focused on such issues as: What are the methodologies for developing standards? Who is involved in developing and implementing them? How are standards updated? How long do they last? What are the costs involved? The following research questions were identified:

1. How can continuous quality improvement (CQI) methods be used to identify and translate into practice the key processes that affect outcomes? Discussants agreed that standards should be based on these key processes.

2. Are current protocols and guidelines having an impact on quality, and what difference do they make in terms of cost and patient outcomes? After a period in which measurement of cost was the major focus there is now interest in measuring quality, and there is a need to put them together.

3. In addition to the medical record, what other aspects of the care process should be captured, compared, and contrasted to improve the quality of care? We can no longer focus only on the medical record. Multiple sources of information need to be tapped.
4. How does the development and application of standards contribute to the adoption of standards by organizations, and how do they influence practice and outcomes? For example, does the credibility of the review by which standards are developed affect their success?

In the workshop on improving the science of QI/QA, discussants were principally interested in increased scientific rigor in QI/QA studies. The following research questions were identified:

1. What methods can be used to improve the reliability and validity of measures of quality in well-controlled investigations? Many measures should be examined in controlled experiments to determine whether they make a difference.
2. What longitudinal measures of quality of care—including the process of care—best represent the patient episode regardless of setting? Patients can move between care settings over time. Are there other sources besides the patients themselves that can provide usable information?
3. In the short term, evaluate and validate commonly used measures, for example, readmissions and outcome tools.

Workgroup III: Organization of Quality Improvement/ Quality Assurance Systems

David B. Nash, M.D., M.B.A., Topic Reporter

Workshop: Delivery Systems

Facilitator: Robert A. Fried, M.D.
Research Discussant: Shoshanna Sofaer, Dr.P.H.

Workshop: Control and Responsibility for Quality Review

Facilitator: James Roberts, M.D.
Research Discussant:
David Hsia, J.D., M.D., M.P.H.

Workshop: Resources for Effective QI/QA

Facilitator: David B. Nash, M.D., M.B.A.
Research Discussant: Gary Filerman, Ph.D.

The workgroup on delivery systems decided that QI, for purposes of its discussion, would not necessarily mean total quality management (TQM), CQI, or QA. Instead, the focus was on quality of care in general, by whatever mechanism. There was considerable initial discussion about which variables were dependent on QI and which were not. Three main questions guided the discussions: (1) Are we going to give QI a chance? (2) If so, is it worth doing? (3) What are the key elements to deal with if we choose to implement QI? Research questions were identified in three main areas:

1. Organizational readiness. This includes individual variables related to institutional and professional culture, which are frequently overlooked; organization and structure of the medical staff —for example, the presence or absence of full-time physicians involved in these activities; whether the organization views QI as a "bottom-line" issue; and whether QI is a reaction to a crisis or the idea of a chief executive officer.
2. Implementation, including: is a certain kind of organizational structure more readily able to adopt QI? If QI is accepted, where is the best place to put it in the organization and with what level of support?
3. Measuring the effects. Some organizations seem to have incorporated QI successfully. What are the characteristics of those organizations, and what lessons can be learned from them?

Discussions in the workshop on control and responsibility for quality review led to the identification of three principal areas for research:

1. Examination of descriptive and comparative studies on Federal and State regulations, accreditation, and community-based efforts involving multiple payers. The goals should be to determine what is being done, what accounts for

variations, what the variations mean, and how processes are changing over time. Discussants also thought it would be useful to examine the regulatory environment in other fields and identify lessons for health care.

2. What effects do variations in processes have? How do they relate to population-based patient outcomes, organizational efficiency, and administrative costs?
3. What are the effects of oversight? Can we identify an optimal relationship between an external review of quality of care in an institution? How does external review stimulate, support, or subvert the QI process? What is the interface between external review and internal processes?

In the workshop on resources for effective QI/QA, participants considered the state of knowledge about the human and fiscal resources devoted to QI and concluded that little is known, although the field is moving rapidly. Likewise there is not much information about the cost of these activities; data are lacking on fixed, variable, or opportunistic costs, as well as on the savings from QI implementation.

The discussants surmised from available information that training of individuals in QI is occurring at multiple levels for a variety of people in health care settings, including nurses, graduate students, administrators, physicians, and ancillary health personnel, and in many different educational forms. However, it appears there are no organized comparisons of the effectiveness of these training programs, nor any good tools to measure their effectiveness. A number of professional organizations are involved in QI training and education, including the Association of University Programs in Health Administration, the American College of Physician Executives, the American College of Medical Quality, the National Association of Health Care Quality, the Institute for Health Care Improvement, and many others. Again, however, there has been no systematic evaluation of the effectiveness of these programs.

Finally, the discussants felt that the Agency for Health Care Policy and Research (AHCPR), although it does not have responsibility for professional curriculum reform, could influence curriculums through such mechanisms as conference and dissertation grants. Four research questions were identified:

1. Which management variables involved in the organization and processes of care have an impact on care outcomes, and how are they measured?
2. What is the fund of knowledge for QI and for teaching it?
3. AHCPR may be able to sponsor research on how to improve the effectiveness of QI education but not necessarily provide funds for developing a curriculum for such training.
4. What models or delivery systems use the tenets of QI most easily and why? Are their outcomes better, cheaper, and reproducible?

Workgroup IV: Using Quality Improvement/Quality Assurance Information

Sheila Leatherman, Topic Reporter

Workshop: Patients as Agents for QI/QA

Facilitator: Paul Nutting, M.D.
Research Discussant: Lisa Sullivan, Ph.D.

Workshop: Purchasers as Agents for QI/QA

Facilitator: Jeanne Keller
Research Discussant: Bruce N. Davidson, Ph.D.

Workshop: Influence of QI/QA on Clinical Decisionmaking

Facilitator: Doris C. Brooker, M.D.
Research Discussant:
Stephen F. Jencks, M.D., M.P.H.

Workshop: Effects of Quality Improvement/ Quality Assurance on Health Care Systems

Facilitator: E. David Buchanan
Research Discussant: Sheila Leatherman

The workshop on patients as QI/QA agents focused on ways to increase the patient's participation in clinical decisionmaking, techniques to enhance patient-provider communication, and methods to learn more about patients and their expectations of the medical encounter. The following topics and research questions were identified:

1. Research is needed on restructuring the patient-provider encounter to give patients a more central role in determining the course of their health care. Specific research questions include: What are the characteristics of patient-provider communication that lead to improved outcomes? How can the medical encounter be structured to enhance effective patient-provider communication?
2. We need to identify and define the data and information currently available to patients and how they are used. Research questions in this area include: How do patients use existing data on the quality and effectiveness of health care? How do they sort among the bewildering array of information currently available? What are the effects of that information on patients' health-related behaviors, health care-seeking behavior, health anxiety levels, and satisfaction with care?
3. We need to learn more about patients' values and expectations of health care and strategies that might provide information to promote attainment of those values and expectations. The workgroup identified these specific research questions, which should not be limited to single care settings: What are patients' values and expectations in health care? What information do they need to make informed decisions? What information about patients' experiences can clinicians and provider organizations use to improve care? Can effective strategies be developed to provide information to patients?

Research questions developed by participants in the workshop on purchasers as agents for QI/QA reflected their awareness that the effectiveness of purchasers depends on developing a partnership with providers. Since QI is a new area of great interest to purchasers, the discussants focused on descriptive research to provide a quick initial assessment of the state of the art and develop a framework for evaluating and communicating results that purchasers have achieved in QI/QA. Three research questions were identified:

1. Are there examples of existing purchaser-provider partnerships for achieving QI/QA goals? An inventory of such partnerships and their characteristics is desirable.
2. What are the characteristics of these purchaser-provider partnerships? Study of the similarities and differences between these groups could produce a typology of such partnerships.
3. What is the relationship between particular characteristics and measures of success in achieving QI/QA goals in such partnerships? For example, is success in achieving the goal of cost savings for the purchaser associated with providing information about quality to consumers?

Participants in the workshop on potential uses of QI/QA information to enhance clinical decisionmaking stressed the importance of uncovering the reasons for successes and failures of previous QI/QA experiments. They also discussed the need to evaluate and compare the merits of various systems interventions. The following research needs were identified:

1. Retrospective and prospective observational studies of natural experiments are needed. Retrospective studies could examine areas where there have been successes—such as laparoscopic cholecystectomy which has changed practice patterns—as well as failures, as in screening practices where wide variations persist. There are opportunities for concurrent prospective studies in many natural experiments that are occurring around the dissemination, proliferation, and use of practice guidelines. These guidelines are being used by commercial insurers, business coalitions, Medicaid, and others.
2. Evaluations are needed of theories underlying interventions to influence clinical decisionmaking at the systems and individual practitioner levels. Systems interventions that should be examined and compared include the health education model, the organizational change model, and the TQM/CQI model.
3. Some thought should be given to convening a conference to identify which organizational and educational factors that facilitate QI/QA can be studied and what methods can be used to study them.

The workshop on the effects of QI/QA on health care systems took in global perspective in developing research themes by viewing QI/QA from a systems viewpoint. Interaction among all players and an in-depth look at previous QI/QA efforts were stressed. The group identified the following research questions:

1. What evidence exists on the effectiveness of QI components? Descriptive retrospective research is needed to examine results to date, using both case studies and anecdotal information. Evaluation research is also needed, with emphasis on prospective studies, on whether QI and QA produce desired results and what the unintended consequences are. These studies could also involve some demonstrations.
2. What are the essential characteristics of the health care delivery systems that have implemented QI? What are the relative contributions of these variables to the successes or failures of QI? Examples of essential characteristics are management's commitment to QI, employee empowerment, active participation of physicians and other health care providers, types of delivery systems (hospitals, managed care, long-term care), and the populations served.
3. Can QI contribute to fostering integrated models of community health service delivery? Does QI provide common measures and tools for linking all "players" (providers, purchasers, policymakers, and so forth)? Can QI make a contribution to the community by improving the health status of individuals or populations, lowering the cost of medical care, and providing decisionmaking support to the community?

Appendix A

Users of Quality Improvement/Quality Assurance Information: Panel and Floor Discussion

The following panel discussion responded to opening addresses at the conference and was intended to set the stage for workshop deliberations and presentations during the conference. Panelists focused on the users of quality improvement/quality assurance (QI/QA) information and discussed the components of a research agenda that would have practice relevance, based on their views of the QI/QA needs of their constituent groups.

Rodney Dueck, M.D. The following are researchable QI/QA questions: What is the technical quality of care that is being provided? How does that quality vary? How do diagnosis, evaluation, and treatment processes vary? How do outcomes vary? Do the leaders of health care institutions understand that quality means more than just technical quality, and that quality of service is also important? How large is the role of fear in unwillingness to report abnormalities or in ordering unnecessary tests? How good is access to medical care? Are medical care workers attuned to the needs of patients as customers? Do they understand their customers? Are patients treated with respect, and are their questions answered? Do patients participate in decisions affecting their care? How can we respond to such challenges while reducing costs and maintaining quality? Do the leaders in health care institutions understand that their employees need to feel appreciated, to have a say in their work, and to experience joy in it? Does management rely on finger-pointing for quality improvement, or is there a process of collegial trust and sharing?

Dr. Dueck is the medical director of the Park Nicollet Medical Center.

Mary Jo Gibson, M.A. A key issue in setting a research agenda is the lack of controlled studies to determine whether continuous quality improvement (CQI) really works. Another research priority should be the use of patients' perspectives as outcome measures—for example, quality of life and perception of pain. In treatment, the preferences of patients should have priority, and the satisfaction of patients requires moving beyond a focus on the "hotel" aspects of the hospital setting. There is a need to examine communication processes between providers and patients and to assess the specific needs and expectations of patients. There is also a need to examine the quality of care in home and community settings as determinants of outcomes for outpatients and patients with chronic illness. How do these different care settings influence both QA and QI? Another critical issue is protection of patients' privacy, since linkage of health data bases will be necessary for cost analysis and other health services research. Research is needed to develop safeguards against improper access to this information.

Ms. Gibson is a senior analyst at the Public Policy Institute of the American Association of Retired Persons.

Robert Hungate, M.B.A. In the future the patient will be the one who drives the system; the professional will no longer be the controller. There is a striking contrast between what is reported in outcomes research studies and public perceptions about outcomes. QI is not a new idea; the system has been trying to improve quality of care for a long time. What is changing is the degree of accountability for results, and the change is dramatic. The change is being driven partly by the news media, but essentially it is based on the need to provide internal control mechanisms. What is evolving is an enhancement of the professional model where the core strength remains the professional-patient relationship, but this is further strengthened by better information technology support. The perceptions of patients are a crucial element of quality and must be built into the system. Communication between providers and patients is critical and must be focused on what the patient needs and expects.

Mr. Hungate is the president of the Physician/Patient Partnerships for Health.

Pamela Waggoner, R.N., M.S.N. As manager of an acute care facility and a lecturer on CQI, I am frequently told by members of my audience that the concept is interesting, but they have difficulty seeing its relevance to their work. There are frequent questions along the lines of, "How will CQI help me in the intensive care unit at 2:00 a.m. when a patient is crashing?" "How does CQI help me do a better job in taking care of my patients?" The basic question is, what are the pragmatic tools of CQI and do they exist globally or must they be derived locally? Answering this question requires formulating research questions that focus on the partnership between caregivers and patients. When hospitals begin to look at that relationship, we will begin to see the cost-effective, quality care patients have been expecting. Another research question to be addressed is how CQI can improve planning for staffing needs, and how the cost and resources required for a certain level or type of care can be assessed effectively?

Ms. Waggoner is the director of Quality Management, DePaul Health Center.

Kathleen N. Lohr, Ph.D. Questions about information technology, the use of large aggregate data sets, and concern about confidentiality are about to become major topics of public debate. The Institute of Medicine is undertaking a study on these issues, and it is already evident that the key issues are related to confidentiality. Reliability and validity are secondary concerns. It appears that protection for data banks in such matters as human immunodeficiency virus infection and mental health is not as good as we might think.

Ms. Lohr is the deputy director of the Division of Health Care Services at the Institute of Medicine.

Floor Discussion

Q: Are there are any situations where studies of outcome data have actually been used to improve the quality of care? Have studies shown an effect?

A: *[Dr. Greenfield]* I am not aware that it has been done yet, although a number of institutions are attempting to incorporate information from outcome studies to improve quality of care. Publication of findings from some of these efforts is imminent.

Q: Does the need to satisfy both internal and external customers have any connection to the "outsider" status of medical staff in hospitals? Should health care professionals also be treated as customers so conditions can be changed to make them better able to take care of patients?

A: *[Dr. Smits]* The problem of treating physicians as customers is that they are intimately involved in the processes, and there is a possibility of conflicts arising between what works well for them and what works well for the patients. As participants in the care process, physicians are a necessary part of improving it. However, there are situations where physicians are the customers and need to be dealt with as such. A good example is surgeons who find institutional delays an impediment to proper care. A virtue of the CQI concept is that it disallows blaming and instead promotes working with others to improve situations. In many cases, when a situation is analyzed, it is clear that no individual is at fault; the problem lies in the processes. Like patients, those in hospitals who are involved in patient care are not always treated well as customers and are beginning to see the situation in those terms. Changing the situation will require time.

Q: Does Dr. Smits suggest that researchers are disenchanted with the Uniform Clinical Data Set (UCDS) that is used by peer review organizations?

A: *[Dr. Smits]* There are concerns about the sheer size of the UCDS, and it is doubtful that a data set that large is accurate. A more parsimonious data set containing the right data elements is more valuable and would put fewer demands on hospitals. If too much information is collected it is not likely to be collected well.

Q: Has there been any improvement in technical care and interpersonal care?

A: *[Dr. Greenfield]* A number of people are working to make interpersonal care as systematic as technical care. In many respects the measurement of interpersonal care is more valid and better refined than many of our medical measurements. Interest in interpersonal care issues is considerable. Several studies are giving equal weight to technical and interpersonal care in their impact on outcomes. In the case of chronic

illnesses, interpersonal care may have a greater effect on outcomes than technical care.

Q: Patients entering health care typically are assessed for such things as pulse, respiration, weight, and blood metabolites, but they are seldom examined for conditions such as depression, intoxication, or availability of transportation, which are being seen as increasingly relevant. Will consideration and measurement of the latter factors ever become a standard part of medical practice as valid clinical data that should be part of the clinical record? If so, what will it take to bring that about?

A: *[Dr. Greenfield]* One way to bring it about is to publish data on these factors in medical journals to bring them to the attention of physicians and ultimately to administrators. Studies in these areas are a potential contribution to medicine, but the quality of measurements for some of these factors need improvement.

[Dr. Smits] It is surprising that so many reports on cataract surgery have dealt with matters such as infection rates, but not on the question of how well patients could see and the quality of their lives. It is important to develop easy ways to measure such factors. There are good measurements for depression but not for such things as whether home and lifestyle factors are helping or hindering treatment success. Elaborate checksheets to address these kinds of issues are not very practical. Simpler screening tools are needed for routine use, with the more elaborate tools used only when they are relevant.

Q: In organizational theory, a distinction between administrative and clinical decisionmaking is relevant to points made by Dr. Smits about problems arising from rigidity in professional roles. Can a focus on quality help us overcome the damaging effects of having two decisionmaking processes in our health care organizations, one administrative and the other clinical, and with neither side understanding the needs of the other?

A: *[Dr. Smits]* CQI offers systematic opportunities to deal with that issue, since it involves physicians and administrators working together to meet the health needs of patients. It is doubtful that administrators in these times are not sensitive to the requirements of the care process, and many physicians have expressed satisfaction about the results obtained from CQI.

Q: Dr. Greenfield suggested that making a difference requires one clinician to challenge the way another clinician practices. How can such barriers to changing physicians' behavior be overcome?

A: *[Dr. Greenfield]* One possible way of dealing with such issues is with managed care, which puts pressure on people to debate. Physicians have to talk to and challenge each other. If they do not do this on their own, the alternative is likely to be administrative regulatory procedures that physicians find onerous. It might be necessary to excuse older physicians from participating in such encounters and concentrate on the newer physicians.

[Dr. Smits] My experience is not consistent with the idea that people cannot change. I know a surgeon who invited his colleagues to study his cases after he observed an increase in complication rates. The colleagues did so and found the cause of the problem. Objective data and a focus on system problems are much better than a focus on individual physician problems. There are a lot of system problems in hospitals that can be fixed without having to blame an individual, although it is necessary to be tough when an individual is at fault.

Q: Is there a role for qualitative research in such quality of care issues as defining roles and behavior and changing attitudes?

A: *[Dr. Greenfield]* There is indeed a role for qualitative studies. We are in a period of quantitative, reductionist, and overly technical analysis, and more balance is needed. We need to keep in mind that much of the quantitative work being done owes its beginning to qualitative and observational work that was not even published.

Q: What are the greatest concerns for quality of health care and what are the prospects for the rest of the century?

A: *[Dr. Dueck]* Health care will comprise 20 percent of the gross national product by the year 2000, and this is a trend that is unsustainable. Decisionmaking is in a paralytic state. I am less concerned about whether physicians will or will not change because I have seen many of them

change and do it gladly. My concern is with the capacity to make the decision for CQI. Medical residents I have lectured about CQI show very little interest or awareness of the subject. Practicing physicians are much the same. The lack of knowledge about management, CQI theory, and its use in health care corporations is disturbing. CQI requires sustained enthusiasm for 5 to 10 years to produce change. People who lack knowledge reject ideas and resist change. Dr. Greenfield described several studies that show the merit of CQI, yet nothing changes; we need to ask why. This leads to further research questions: What are leaders doing to educate themselves about CQI? To what degree do medical schools incorporate it in their training? Do management leaders understand it and their role in CQI?

Q: Given the limited resources at Agency forHealth Care Policy and Research and the research community in general, what are the high-priority research topics for CQI?

A: *[Ms. Waggoner]* About 50 percent of health care institutions will embark on CQI initiatives over the next 3 to 5 years. The alarming fact is that about 90 percent of those initiatives will fail. In my institution, when we look at an investment of hundreds of thousands of dollars in CQI and know it could fail, we want information on successful methodologies. So I think there is a need for research on hospital cultures. The process changes in CQI are not individualistic, yet we have independent physicians in the institution. When we looked at our proposal options, we found enthusiasm but no data on successes to provide guidance. Studies of CQI successes and failures are needed so people can learn from them.

Q: How might we think about consortia and support of research on quality among sectors? How might they work and communicate? Could corporations help fund this?

A: *[Mr. Hungate]* Benefit managers do try to provide good health benefits for employees but are limited primarily to plan design in their ability to do so. Employees cannot make valid decisions about health care needs during open enrollment unless they have a preexisting condition and knowledge of how plans manage that condition. Open enrollment does let people move from one plan to another, but they usually do not study these changes. This could be researched to help design better benefit plans that would stimulate QI.

Q: What is the difference between CQI, total quality management (TQM), and total quality improvement? Are they the same thing, and does it matter?

A: *[Dr. Dueck]* These acronyms denote various corporate responses to quality issues. What they all have in common is an orientation to the customer, taking time to understand the customer, and working continuously to align processes to the customer's needs and expectations. Another thing they have in common is actions to bring about cooperation, collaboration, absence of fear, and a sense of teamwork and trust among caregivers. They also share statistical thinking, process-oriented analytical problem solving, and application of the scientific method to decisionmaking.

[Dr. Palmer] The concepts overlap. TQM is more a strategy for quality and implies cultural and organizational change. CQI deals more with the actual business of improvement.

Q: In looking at quality, client satisfaction is a main focus. My question is about methodology. Are different methodologies needed for surveying clients for level of satisfaction when the care is in the home?

A: *[Dr. Lohr]* The Institute of Medicine's study of quality assurance in Medicare considered home health care a high priority area. The methods and the questions to be asked in home health care are different, because it is a distinct population with a distinct set of problems.

Appendix B

Reaction to Workshop Recommendations for Research Priorities: Panel and Floor Discussion

The members of this panel reacted to the presentations and research priorities identified in the workshop reports.

Pamela Waggoner, R.N., M.S.N., C.C.R.N.
A healthy skepticism was evident in the conference discussions about continuous quality improvement (CQI). The health care field has embraced the concept of continuous improvement in the past year and a half and appears willing to invest a lot of money in a process that so far has not been validated by rigorous scientific inquiry. On a more promising note, representatives of various health care interest groups demonstrated a collaborative spirit and interest in working toward continuous improvement in health care.

Although the conference participants did an impressive job, with much discussion about processes of health care delivery, a number of important questions and issues merit further investigation. For example, we should consider the process of identifying specific elements of care used during an episode of illness. We need to ask, "How does the sequence of specific care activities affect outcome? Can continuous improvement affect episodes of care to the same extent that it can affect episodes of illness?" The outcomes are not the same for an episode of care and an episode of illness, and it is possible that continuous improvement could affect one more than the other.

Another important question is which methods can accelerate the processes of CQI, a transformation that now can take 5 to 10 years. It is not clear that the health care industry has 5 to 10 years to achieve this transformation. Are there ways to accelerate the process?

Many efforts to implement CQI in components of the health care industry seem to fail after about 18 months to 3 years. Can these failures be predicted, and can steps be taken to prevent failure? Can the health care industry learn anything from similar failures that have occurred in other kinds of industries?

Several of the workshops gave attention to the most effective ways to use continuous improvement data, not only to change care practices but also to change expectations of consumers and payers. A question needing further investigation is whether outcomes data should be used as tools for negotiating preferred provider organization and health maintenance organization contracts in acute-care and long-term care settings. An important topic that was not addressed by any of the work groups concerns the impact of CQI on the industries that design the technologies of medical care.

Specific patient populations were considered by discussants in the context of CQI, but it would have been helpful if the role of hospitals also had been considered. Hospitals need to take specific patient populations into account in implementing CQI and in designing outcomes measures, practice guidelines, and evaluation criteria. They also need to examine delivery processes, review criteria, and outcome criteria for high volume, high-risk activities such as coronary bypass surgery and total hip replacement.

Another area that merits further attention is the impact of comorbidity on outcomes. How can guidelines account for the impact of comorbidity on outcomes?

Ms. Waggoner is Director, Quality Management, DePaul Health Center, Daughters of Charity National Health System

Robert Hungate, M.B.A. From the perspective of health care purchasers, it is clear that health care is on the threshold of profound changes. There is palpable tension in the purchaser community about the state of the health care industry. Frustrations are intense and are growing. The need for improvement is unquestionable when, for example, the rate of cesarean sections is so variable geographically and generally is judged to be excessive in most places. Such shortcomings have been apparent for a long time.

From the perspective of patients, a number of recommendations from the workshops merit strong endorsement and support. The recommendations on use of information technology for quality assurance and quality improvement (QI) merit support. We do not always need new information; rather we must learn how to use the information we already have more effectively.

It is always surprising to hear recommendations for research on why people do things. The answer seems obvious—people change for their self interest, and they adopt practices that they think will make their lives better. I come from an industry that has marketed information systems, and it is clear that people do not buy something unless they believe it is better than what they have. Once people come to realize that something can make their lives better, no research is needed on how to disseminate information about it. It simply happens. Laparoscopic cholecystectomy is a good example. The way to get something disseminated is to make it good. Tinkering at the margins is not what is needed. What is needed is real action on things that will make a difference, such as improving information systems.

With regard to the recommendations for education, the new generation that will take over the health care industry could be called "the Nintendo generation," and it has a very different set of skills and behaviors than those who run it now. In 15 years, they will be using the tools that are evolving now, and our task is to facilitate that transition. Thus, education for them is of major importance.

The recommendations concerning patients as agents for QI also are of major importance, for it is in the area of the doctor-patient relationship where major improvement in quality of care will take place.

There is a need to shift our focus from health care to health itself. Health can be measured in populations; this is the standard public health approach. The purchaser community continues to concentrate on health care costs, however, not on the health of the work force. The health of the work force is actually more critical to an employer than health care costs. There is much more to be lost from lack of motivation in unhealthy workers than from the cost of health care. An increased focus on community health can help shift the focus of health care purchasers.

Mr. Hungate is President, Physician/Patient Partnerships for Health.

Mary Jo Gibson, M.A. Quality of care is an important component of a health care reform proposal being prepared by the American Association of Retired Persons (AARP). AARP is interested in health care reform for the benefit of all Americans, not just its own members. Its proposal includes universal coverage, cost containment, quality assurance, and long-term care.

Dr. Leatherman's concern about people outside the health care system is well founded. Patients and purchasers were considered as agents of change in workshop discussions, but there are 36 million Americans without health insurance, and issues of quality of care alone are somewhat irrelevant to them. There are also at least 20 million more Americans who are underinsured. The needs of this large group should be studied as a quality of care issue.

In the area of information technology, workshop emphasis on the roles of technology, policy, legislation, and public opinion in protecting privacy and confidentiality is consonant with the AARP's concerns. Protecting the privacy of data base information is an important area for research. Canada and other countries have used unique patient identifiers in data bases for some time, and it may be worthwhile to study their systems to determine how well they protect privacy. Another highly salient question emerging from the information technology sessions was how to incorporate patient-specific values and preferences into decision support systems.

The discussion sessions on methods and measures examined the question of longitudinal measures needed to follow patients across care settings. Research on tracking patients through the whole system—including post-acute and long-term care as well as acute care—should be given high priority.

The session on control and responsibility for quality review raised questions with many policy implications. Of particular interest is the relationship of State and Federal regulatory activities to QI. A number of important questions were raised in the session. What are the effects of oversight? In what settings or circumstances should existing inspection methods be retained? How does external review stimulate, support, or subvert the QI process?

It was also pleasing to see the workshop focus on whether the CQI process works and whether it produces unintended adverse consequences. The recommendation to study restructuring of the patient-provider encounter to improve communication was appropriate. However, it is also important

to examine the effects of differing payment and delivery systems (such as various forms of managed care) on this encounter, as well as how the characteristics of physicians and patients influence the encounter. Finally, drawing upon research in fields such as education and psychology might help us better understand and influence both physician and patient behaviors.

Ms. Gibson is Senior Analyst, Public Policy Institute, American Association of Retired Persons.

Rodney R. Dueck, M.D. Two important themes emerged during the conference. First is the importance of continued learning. Much of what we need to learn about QI in health care exists in literature other than that usually studied by health care professionals. Familiarity with that literature may provide shortcuts to useful knowledge. Second is the concept of systems thinking. Whether we use a public health perspective or focus on the community, we are thinking in terms of the whole. In contrast, optimizing the parts at the expense of the system as a whole could be very costly. Our paradigms of individuality and entrepreneurship are valuable and powerful, but they also can blind us to the value and power of cooperation and systems thinking. According to Deming's theory of management, optimization of the parts at the expense of the whole leads to decline—optimization of the whole benefits all, over the long term.

Several of the workshop recommendations are of direct interest to physicians. In particular, physicians are likely to be very receptive to the idea of a decision support system. Although it is important not to diminish professional autonomy in caring for a patient, it also is important to reduce the incidence of unintended variation in providing care. Physicians want to do a good job and are not averse to being helped by a support system.

The recommendation to examine QI successes and failures in the real world, and to learn from them, is especially valuable. Understanding the causes of success and failure can accelerate the process of instituting CQI.

In the area of quality review criteria, the most important element is the nature of the relationship between reviewers and those being reviewed. The process should be nonaccusatory and educational, and it should focus on improving the system as a whole and not on finding individuals to blame. Accountability is important, but it is most powerful when it is voluntary, and a teaching and support mode will lead to more receptive providers.

In developing standards, it is important that the standards be credible and respectable. Pulse oximetry in general anesthesia is an excellent example of a standard. It has a powerful impact on the lives of patients by reducing complication rates and thus gives credibility to the agency or institution that enforces it. Vague standards, which are perceived as arbitrary and capricious, create confusion, resentment, and loss of movement.

Another research question developed during the conference concerns the effects of regulatory oversight on QI. Oversight and QI are not necessarily incompatible if there is trust between providers and regulators, but very little, if any, trust exists between them at this time. The best approach to overcoming this problem is teaching, improving systems, and asking for voluntary cooperation. Measurement and feedback without threat of reprisal can be very helpful.

Regarding the recommendation to study the experiences of other industries in QI, an enormous literature base exists on this that could be adapted to the health care industry and medical thinking.

On patients as agents for change, it is critical that physicians learn to understand the views of patients. Anything that can be done to facilitate that understanding is a crucial first step. The second step is for physicians to examine how their processes are discordant with the thinking and expectations of patients.

Key issues in the area of purchasers as agents for change are the concepts of partnership and optimizing the system as a whole. Other industries are ahead of the health care industry in implementing these concepts.

As others have noted, the problem of people without health insurance is major and must be solved. Its solution may come through development of a systems approach and a cooperative spirit in the health care industry.

Dr. Dueck is Medical Director, Park Nicollet Medical Center.

Floor Discussion

Q: A recurring theme in this conference is the need for access to data on health care quality. Peer review organizations (PROs) in every State collect and analyze large amounts of information on health care quality, although they tend to use it to identify bad performers. Could better use be made of PRO information resources for CQI, and could the PROs themselves evolve into instruments for CQI?

Discussion among the panelists and members of the audience brought out the following points:

- Many PROs have been moving from a focus on punitive action toward use of data for improving care. As the health care industry in general moves toward QI, it will not be necessary to "twist the arms" of the PROs to shift their focus.
- In addition, there has been a trend in recent years for PROs to get involved in research on technology assessment and quality of care, suggesting that they could become an important resource for CQI. The Agency for Health Care Policy and Research is promoting this transition from affixing blame to surveillance and education. A key question, however, is whether it is possible for an external organization such as a PRO to relate to providers in an educational manner, and, if so, what would be necessary to accomplish this. The existence of PROs in every State, each doing things in different ways, does create opportunities for "natural experiments" which could help to answer that question.

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